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Contents

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Concordance of Text Message Ecological Momentary Assessment and Retrospective Survey Data Among Substance-Using Men Who Have Sex With Men: A Secondary Analysis of a Randomized Controlled Trial

Christopher Rowe[1], MPH; Jaclyn Hern[1], MPH; Anna DeMartini[1], MPH; Danielle Jennings[1], MPH; Mathew Sommers[1], MSc; John Walker[1], MSN, FNP-C; Glenn-Milo Santos[1,2], MPH, PhD

[1]San Francisco Department of Public Health, San Francisco, CA, United States

[2]University of California, San Francisco, San Francisco, CA, United States

Corresponding Author:
Christopher Rowe, MPH
San Francisco Department of Public Health
25 Van Ness, Suite 500
San Francisco, CA, 94102
United States
Phone: 1 415 437 6283
Fax: 1 415 431 4039
Email: chris.rowe@sfdph.org

Abstract

Background: Alcohol and illicit drug use is more prevalent among men who have sex with men (MSM) compared to the general population and has been linked to HIV transmission in this population. Research assessing individual patterns of substance use often utilizes questionnaires or interviews that rely on retrospective self-reported information, which can be subject to recall bias. Ecological momentary assessment (EMA) is a set of methods developed to mitigate recall bias by collecting data about subjects' mental states and behaviors on a near real-time basis. EMA remains underutilized in substance use and HIV research.

Objective: To assess the concordance between daily reports of substance use collected by EMA text messages (short message service, SMS) and retrospective questionnaires and identify predictors of daily concordance in a sample of MSM.

Methods: We conducted a secondary analysis of EMA text responses (regarding behavior on the previous day) and audio computer-assisted self-interview (ACASI) survey data (14-day recall) from June 2013 to September 2014 as part of a randomized controlled trial assessing a pharmacologic intervention to reduce methamphetamine and alcohol use among nondependent MSM in San Francisco, California. Reports of daily methamphetamine use, alcohol use, and binge alcohol use (5 or more drinks on one occasion) were collected via EMA and ACASI and compared using McNemar's tests. Demographic and behavioral correlates of daily concordance between EMA and ACASI were assessed for each substance, using separate multivariable logistic regression models, fit with generalized estimating equations.

Results: Among 30 MSM, a total of 994 days were included in the analysis for methamphetamine use, 987 for alcohol use, and 981 for binge alcohol use. Methamphetamine (EMA 20%, ACASI 11%, P<.001) and alcohol use (EMA 40%, ACASI 35%, P=.001) were reported significantly more frequently via EMA versus ACASI. In multivariable analysis, text reporting of methamphetamine (adjusted odds ratio 0.06, 95% CI 0.04-0.10), alcohol (0.48, 0.33-0.69), and binge alcohol use (0.27, 0.17-0.42) was negatively associated with daily concordance in the reporting of each respective substance. Compared to white participants, African American participants were less likely to have daily concordance in methamphetamine (0.15, 0.05-0.43) and alcohol (0.2, 0.05-0.54) reporting, and other participants of color (ie, Asian, Hispanic, multi-racial) were less likely to have daily concordance in methamphetamine reporting (0.34, 0.12-1.00). College graduates were more likely to have daily concordance in methamphetamine reporting (6.79, 1.84-25.04) compared to those with no college experience.

Conclusions: We found that methamphetamine and alcohol use were reported more frequently with daily EMA texts compared to retrospective ACASI, concordance varied among different racial/ethnic subgroups and education levels, and reported substance use by EMA text was associated with lower daily concordance with retrospective ACASI. These findings suggest that EMA methods may provide more complete reporting of frequent, discrete behaviors such as substance use.

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KEYWORDS

data collection; cell phones; drug users; drinking behavior; homosexuality, male

Introduction

Use of alcohol and illicit drugs (ie, substance use) is a major contributor to the global burden of disease [1,2] and is more prevalent among men who have sex with men (MSM) than among the general population [3,4]. In a 2011 national sample of MSM across 20 US cities, 85% reported drinking alcohol and 50% reported binge drinking (having 5 or more alcoholic beverages on a single occasion) in the past 30 days and 49% reported using noninjection drugs in the past 12 months [3]. Heavy alcohol use and the use of noninjection drugs, particularly methamphetamine, have been linked to the transmission and acquisition of HIV among MSM, who continue to be more affected by HIV than any other demographic group in the United States [5]. Understanding alcohol and substance use behaviors among MSM at high risk for HIV is essential for effectively informing efforts to reduce HIV transmission and improve overall health in this population.

Research assessing individual patterns and the frequency of alcohol and substance use often utilizes questionnaires or interviews that rely on retrospective self-reported information. A major limitation of these methods is that information recalled from memory is prone to distortion, which can affect the reliability of collected data [6,7]. Ecological momentary assessment (EMA) is a set of methods developed to mitigate recall bias by collecting data about subjects' mental states and behaviors on a near real-time basis [7,8]. EMA methods involve repeated assessments within subjects' natural environments and routines and vary widely in design [9]. Studies using EMA methods, for example, may combine participant-initiated data reporting with randomly administered assessments throughout the day, or administer assessments at regular intervals to achieve abbreviated recall windows ranging from hours to an entire day [9-13]. Moreover, these methods can employ written or electronic diaries, physiological sensors, or mobile devices, such as mobile phones [7]. The popularity and near-universal prevalence of mobile phones makes them a powerful conduit for data collection, especially with the simplicity of text messaging (short message service, SMS) [14]. Furthermore, EMA may be particularly effective for substance use research due to the episodic and discrete nature of substance use behavior, which makes it better suited for real-time data collection than behaviors or states that are more ongoing [9]. Despite concerns regarding the ability and willingness of substance-using populations to adhere to the high-engagement requirements of EMA methods, a growing body of literature has demonstrated the feasibility, acceptability, and reliability of EMA among those who engage in substance use [15-21].

Although it has shown to be successful, EMA remains underutilized in substance use and HIV research. To date, relatively few studies have employed EMA methods to assess substance use patterns among MSM, and none have assessed the concordance of information reported using EMA with retrospective questionnaires among this population. To better understand the utility of different data collection methods among substance-using MSM, we aimed to assess the concordance between daily reports of substance use collected by EMA text messages and retrospective questionnaires, and to identify predictors of daily concordance.

Methods

Study Sample

We conducted a secondary analysis of EMA text responses and audio computer-assisted self-interview (ACASI) survey data from June 2013 to September 2014 as part of a randomized controlled trial assessing the feasibility, acceptability, and tolerability of a pharmacologic intervention to reduce methamphetamine and alcohol use among nondependent MSM in San Francisco, California [22]. Active recruitment efforts included outreach at municipal sexually transmitted infection (STI) and HIV clinics, MSM community-based organizations, gay bars and events, and syringe access programs. Passive recruitment efforts included flyers at active recruitment sites and advertisements in local newspapers, gay print media, and on social media. Eligibility criteria included: self-reported methamphetamine use at least 2 times per month, binge alcohol use at least once per week, methamphetamine or alcohol use concurrent with anal intercourse in the past 3 months, and a desire to reduce or discontinue methamphetamine and alcohol use. Additionally, participants were required to have a mobile phone that could send and receive text messages. All study participants provided informed consent and study procedures were approved by the Committee on Human Research, University of California, San Francisco.

Data Collection

EMA data were collected via daily text messages. Beginning the day after a baseline visit, participants were sent daily text messages asking about their behaviors on the previous day. They were asked whether they had taken the study drug, used methamphetamine, or used alcohol (and if so, the number of alcoholic drinks consumed). Participants received this text message series every day until the conclusion of the follow-up period (approximately 2 months). As reimbursement for their time, participants received a $1 stipend for each day that they completed the text message series.

ACASI surveys were administered at baseline and approximately every 2 weeks for a total of 5 visits. Each ACASI survey asked participants whether or not they had engaged in the following behaviors on each of the preceding 14 days: methamphetamine use, alcohol use, and binge alcohol use. To enhance recall, participants were provided with the exact calendar dates of the preceding 14 days as part of the assessments for these 3 behaviors, using a modified timeline follow-back approach.

Additional data collected at baseline included: demographic characteristics, including race, age, and highest level of education achieved; number of days in the past 4 weeks during which the participant engaged in binge alcohol use; and the frequency of methamphetamine use in the past 4 weeks as either less than one day per month or a selection of 1 through 4 days per month and 2 through 7 days per week. The frequency of methamphetamine use was then converted into a continuous variable to correspond to the number of days in the past 4 weeks during which methamphetamine was used. Due to our small sample size and the limited number of participants who identified as a race other than white or African American (Latino/Hispanic n=5, Asian American or Pacific Islander n=2, mixed or multi-racial n=2), participants who were neither white nor African American were combined into an "other" race category.

Reporting and Concordance Measures

In the analysis for each substance, days were only included for which both an ACASI recall response and an EMA text response were present. Such that, if a participant did not complete the text series on a given day, did not complete an ACASI, or if study visits were scheduled more than 14 days apart (resulting in gaps in ACASI recall), concordance could not be assessed due to missing data. These days were therefore excluded in the concordance analysis.

Pooled for the entire sample, the total number and proportion of days on which methamphetamine use, alcohol use, and binge alcohol use were reported were calculated for both ACASI and EMA. McNemar's tests were used to assess differences in reported frequencies of methamphetamine, alcohol, and binge alcohol use between EMA text and ACASI modified timeline follow-back data.

The total number and proportion of days for which ACASI and EMA responses matched for each substance (ie, concordant responses) were calculated. This included both concordant positive responses (ie, days that methamphetamine use, alcohol use, or binge alcohol use were reported through both ACASI and EMA) and concordant negative responses (ie, days that no methamphetamine use, no alcohol use, or no binge alcohol use was reported through both ACASI and EMA). We also calculated the phi coefficient, which is equivalent to Pearson's correlation coefficient when applied to binary variables, between ACASI and EMA responses.

Multivariable Analysis

For our primary multivariable analysis, we used multivariable logistic regression models, fit with generalized estimating equations that accounted for clustering within-subject, to assess the likelihood of having concordant responses on a given day for methamphetamine use, alcohol use, and binge alcohol use. All models included demographic and behavioral characteristics as time-invariant covariates and the number of days elapsed since the baseline visit as a time-varying covariate. Overall, 3 models (one for each substance-specific concordance outcome) included a time-varying binary covariate indicating whether or not the relevant substance was reported by EMA text on the day being assessed. Each substance-specific model included only the time-varying EMA text response covariate for the substance being assessed in that model (ie, methamphetamine, alcohol, or binge alcohol).

In sensitivity analyses, 3 alternative models (one for each substance-specific concordance outcome) included a covariate indicating the number of alcohol beverages reported by EMA text on the day being assessed. In the model assessing concordance of methamphetamine use reporting, both the binary covariate indicating any methamphetamine use and the continuous covariate indicating the number of drinks consumed were included. In the models assessing concordance of alcohol and binge alcohol use reporting, only the covariate indicating the number of drinks consumed was included. All other covariates in these 3 models were the same as in the primary models.

Results

Study Sample Characteristics

As presented in Table 1, our study sample of 30 participants was racially/ethnically diverse: 12 participants (40%) were white, 9 (30%) were African American, and 9 (30%) identified as any other race/ethnicity. The mean age was 43 (SD 9.3) and 26 (87%) had completed at least some college education, with 9 (30%) having a Bachelor's degree or higher. The average number of days of substance use in the 4 weeks prior to baseline was 6 (SD 4.6) for methamphetamine, 13 (SD 7.6) for alcohol, and 7 (SD 7.2) for binge alcohol.

Table 1. Demographic and substance use characteristics of study participants (n=30).

		n (%) or mean (SD)
Age, mean (SD)		43 (9.3)
Race	White	12 (40.0)
	African American	9 (30.0)
	Other	9 (30.0)
Education	High school diploma or less	4 (13.3)
	Some college	17 (56.7)
	Bachelor's degree or higher	9 (30.0)
Days of Substance Use in Last 4 Weeks at Baseline	Methamphetamine, mean (SD)	6 (4.6)
	Alcohol, mean (SD)	13 (7.6)
	Binge alcohol, mean (SD)	7 (7.2)

ACASI and EMA Text Compliance

All compliance measures are reported in Table 2. In total, 30 participants completed 143 (95%) biweekly ACASI surveys out of the intended 150. Twenty-four participants (80%) completed all 5 intended surveys, 5 participants (17%) completed 4 surveys, and 1 participant (3%) completed 3 surveys. Because initiation of daily text messages did not begin until the day after the participants' first ACASI (with the exception of 1 participant who initiated daily text messages early and provided 4 days of EMA recall prior to their first ACASI), all but these 4 recall responses from participants' first ACASI surveys were not relevant to this analysis. Across the 30 participants and including the aforementioned 4 additional days, a total of 1469 (mean per participant 49, SD 7.7) days of methamphetamine use reporting and 1462 (mean per participant 49, SD 7.9) days of alcohol and binge alcohol use reporting were collected via participants' noninitial ACASI surveys.

Of the 1469 and 1462 days of ACASI reporting for methamphetamine and alcohol/binge alcohol use, respectively, EMA text responses were collected on 994 days (68%) for methamphetamine use, 987 (68%) for alcohol use, and 981 (67%) for binge alcohol use. For each substance, EMA text reporting was not available for 156 (11% for each substance) days due to delayed initiation or technical issues and 319 (22% for each substance) days due to participant nonresponse. Of days for which ACASI reporting was available, the average number of days of EMA text data available was 33.1 for methamphetamine use (range 10-55, SD 13.8), 32.9 for alcohol use (range 10-55, SD 13.8), and 32.7 for binge alcohol use (range 10-55, SD 13.9). As a percentage of the days of ACASI data per participant, these numbers correspond to 67.2% for methamphetamine use (range 19-98, SD 24.2), 67.1% for alcohol use (range 19-98, SD 24.1), and 66.6% for binge alcohol use (range 19-98, SD 24.2).

Reporting and Concordance Measures

A total of 994 days were included in the analysis for methamphetamine use, 987 for alcohol use, and 981 for binge alcohol use (see Figure 1). There were significant differences in the proportion of days on which methamphetamine and alcohol use were reported by text versus ACASI ($P<.05$). The frequencies reported by EMA text and ACASI, respectively, were 20% and 11% for methamphetamine use ($P<.001$) and 39% and 35% for alcohol use ($P=.005$). There was no significant difference in the proportion of days on which binge alcohol use was reported by text versus ACASI ($P=.58$). Of the concordant responses for each substance, the majority were reports of no substance use (92% for methamphetamine use, 67% for alcohol use, and 87% for binge alcohol use). The phi coefficients were 0.35 for methamphetamine use, 0.49 for alcohol use, and 0.47 for binge alcohol use.

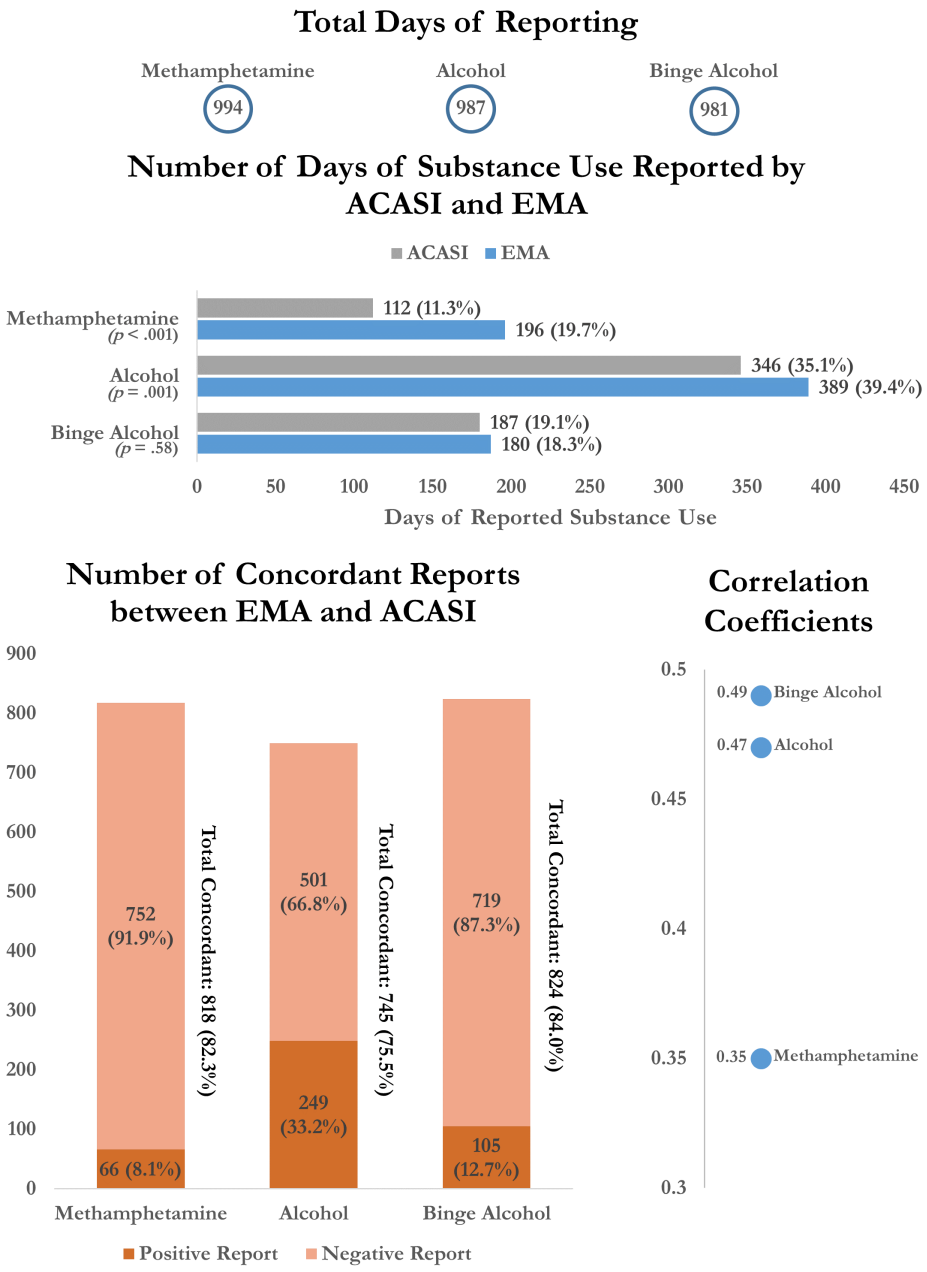
Table 2. ACASI and EMA text message reporting compliance.

			n (%) or mean (range, SD)
ACASI Compliance	Overall Compliance of Biweekly ACASI Surveys	Total number intended	150
		Total number completed	143 (95.3)
	Number of ACASI Surveys Completed by Study Participants (n=30)	5 (100% compliance)	24 (80.0)
		4 (80% compliance)	5 (16.7)
		3 (60% compliance)	1 (3.3)
	Total Number of Days of ACASI Data[a]	Methamphetamine use	1469
		Alcohol use	1462
		Binge alcohol use	1462
	Number of Days of ACASI Data Per Participant[a]	Methamphetamine use mean (range, SD)	49 (28-56, 7.7)
		Alcohol use mean (range, SD)	49 (28-56, 7.9)
		Binge alcohol use mean (range, SD)	49 (28-56, 7.9)
EMA Text Message Compliance[b]	Methamphetamine Use Reporting (Pooled for Entire Sample)	Complete text response	994 (67.7)
		Missing text response	319 (21.7)
		Delayed initiation or system issue	156 (10.6)
	Alcohol Use Reporting (Pooled for Entire Sample)	Complete text response	987 (67.5)
		Missing text response	319 (21.8)
		Delayed initiation or system issue	156 (10.7)
	Binge Alcohol Use Reporting (Pooled for Entire Sample)	Complete text response	987 (67.5)
		Missing text response	319 (21.8)
		Delayed initiation or system issue	156 (10.7)
	Number of Days of EMA Text Data Per Participant	Methamphetamine use mean (range, SD)	33.1 (10-55, 13.8)
		Alcohol use mean (range, SD)	32.9 (10-55, 13.8)
		Binge alcohol use mean (range, SD)	32.7 (10-55, 13.9)
	Days of EMA Text Data as Percentage of Days of ACASI Data Per Participant	Methamphetamine use mean (range, SD)	67.2 (19-98, 24.2)
		Alcohol use mean (range, SD)	67.1 (19-98, 24.1)
		Binge alcohol use mean (range, SD)	66.6 (19-98, 24.2)

[a]With the exception of 4 days for a single participant, recall responses from participants' first ACASI survey were not relevant to this analysis because EMA text messaging did not begin until the day after the first survey was completed. These are excluded from the total number of days of ACASI data available.

[b]EMA text message compliance was assessed as the proportion of the number of days of ACASI data available.

Figure 1. Reporting and concordance measures for entire pooled sample (n = 30).



Multivariable Analysis

The results of the generalized estimating equation fitted multivariable logistic regression models are presented in Tables 3-6. In the primary model assessing methamphetamine reporting (Table 3), text reporting of any methamphetamine use was negatively associated with daily concordance in methamphetamine reporting (adjusted odds ratio 0.06, 95% CI 0.04-0.10). African American (0.15, 0.05-0.43) and other participants of color (ie, Hispanic/Latino, Asian American and Pacific Islander, mixed or multi-racial individuals) (0.34, 0.12-1.00) were also less likely to have daily concordance in methamphetamine reporting compared to white participants. Participants who had graduated from college had a greater odds of methamphetamine reporting concordance (6.79, 1.84-25.04) compared to those with no college experience. In the sensitivity analysis that included both the text reports of any methamphetamine use and number of alcoholic drinks, number of drinks was not independently associated with methamphetamine reporting concordance and the coefficient estimates of all other covariates were not significantly different than those in the primary model (P=0.69, data not shown).

In the primary model assessing alcohol reporting (Table 4), text reporting of any alcohol use was negatively associated with daily concordance in reporting of alcohol use (0.50, 0.34-0.73). African American participants were less likely to have daily concordance in alcohol use reporting compared to white participants (0.18, 0.06-0.57). In the sensitivity analysis that included the number of alcoholic drinks reported by text, number of drinks was not independently associated with alcohol reporting concordance and coefficient estimates of the other covariates were not significantly different than those in the primary model (P=0.11, data not shown).

In the primary model assessing binge alcohol reporting (Table 5), text reporting of any binge alcohol use was negatively associated with daily concordance in reporting of binge alcohol use (0.27, 0.17-0.42). In the sensitivity analysis that included the number of alcoholic drinks reported by text (Table 6), number of drinks was negatively associated with concordance in binge alcohol use reporting (0.89, 0.84-0.94). Also, in this model, African American participants were less likely to have daily concordance in binge alcohol use reporting compared to white participants (0.25, 0.07-0.87).

Table 3. Multivariable logistic regression model, fit with generalized estimating equations, assessing daily EMA-ACASI concordance in methamphetamine reporting (n=994).

Variable		Daily EMA-ACASI Concordance in Methamphetamine Reporting		
		OR	(95% CI)	*P*-value
Text Report of Any Methamphetamine Use		0.06	(0.04-0.10)	<.001
Race	White		Reference	
	African American	0.15	(0.05-0.43)	<.001
	Other[a]	0.34	(0.12-1.00	.049
Age		1.02	(0.97-1.08)	.46
Education	High school graduate or less		Reference	
	Some college	2.17	(0.81-5.80)	.12
	College graduate or more	6.79	(1.84-25.04)	.004
Baseline Days of Meth Use in Past 4 Weeks		1.01	(0.92-1.10)	.88
Baseline Days of Binge Drinking in Past 4 Weeks		0.98	(0.93-1.04)	.52
Day of Follow-Up		1.00	(0.99-1.02)	.55

[a]Includes Hispanic/Latino, Asian American or Pacific Islander, and mixed or multi-racial individuals.

Table 4. Multivariable logistic regression model, fit with generalized estimating equations, assessing daily EMA-ACASI concordance in alcohol reporting (n=987).

Variable		Daily EMA-ACASI Concordance in Alcohol Reporting		
		OR	(95% CI)	*P*-value
Text Report of Any Alcohol Use		0.50	(0.34-0.73)	<.001
Race	White		Reference	
	African American	0.18	(0.06-0.57)	.004
	Other[a]	0.43	(0.17-1.08)	.07
Age		1.02	(0.97-1.07)	.40
Education	High school graduate or less		Reference	
	Some college	0.79	(0.27-2.32)	.67
	College graduate or more	1.17	(0.31-4.36)	.81
Baseline Days of Meth Use in Past 4 Weeks		1.08	(0.99-1.18)	.07
Baseline Days of Binge Drinking in Past 4 Weeks		1.03	(0.96-1.10)	.38
Day of Follow-Up		1.02	(1.01-1.03)	<.001

[a]Includes Hispanic/Latino, Asian American or Pacific Islander, and mixed or multi-racial individuals.

Table 5. Multivariable logistic regression model, fit with generalized estimating equations, assessing daily EMA-ACASI concordance in binge alcohol reporting (with text report of any binge alcohol use predictor) (n=981).

Variable		Daily EMA-ACASI Concordance in Binge Alcohol Reporting		
		OR	(95% CI)	*P*-value
Text Report of Any Binge Alcohol Use		0.27	(0.17-0.42)	<.001
Race	White		Reference	
	African American	0.35	(0.11-1.31)	.08
	Other[a]	0.69	(0.22-2.18)	.53
Age		1.02	(0.97-1.09)	.41
Education	High school graduate or less		Reference	
	Some college	1.68	(0.52-5.38)	.39
	College graduate or more	2.67	(0.64-11.1)	.18
Baseline Days of Meth Use in Past 4 Weeks		1.05	(0.95-1.17)	.30
Baseline Days of Binge Drinking in Past 4 Weeks		0.97	(0.91-1.03)	.33
Day of Follow-Up		1.01	(1.00-1.02)	.26

[a]Includes Hispanic/Latino, Asian American or Pacific Islander, and mixed or multi-racial individuals.

Table 6. Multivariable logistic regression model, fit with generalized estimating equations, assessing daily EMA-ACASI concordance in binge alcohol reporting (with text report of number of drinks predictor) (n=981).

Variable		Daily EMA-ACASI Concordance in Binge Alcohol Reporting		
		OR	(95% CI)	*P*-value
Text Report of Number of Drinks		0.89	(0.84-0.94)	<.001
Race	White		Reference	
	African American	0.25	(0.07-0.87)	.03
	Other[a]	0.68	(0.22-2.11)	.50
Age		1.05	(0.99-1.11)	.14
Education	High school graduate or less		Reference	
	Some college	1.40	(0.45-4.34)	.56
	College graduate or more	2.29	(0.55-9.54)	.26
Baseline Days of Meth Use in Past 4 Weeks		1.07	(0.97-1.19)	.16
Baseline Days of Binge Drinking in Past 4 Weeks		0.98	(0.91-1.04)	.46
Day of Follow-Up		1.01	(0.99-1.02)	.35

[a]Includes Hispanic/Latino, Asian American or Pacific Islander, and mixed or multi-racial individuals.

Discussion

Principal Findings

We found that substance use was reported more frequently using daily text messaging compared to retrospective questionnaires, with the greatest differential in the reporting of methamphetamine use. Daily concordance between EMA and questionnaire self-reports was not homogenous across participants; specifically, congruent reports were less likely among non-white participants and more likely among those who had graduated from college. Lastly, on days in which each substance was reported to have been used via EMA text response, use was significantly less likely to be reported in the ACASI questionnaire. These findings have implications for both the design and interpretation of substance use research among MSM.

In general, EMA captured more frequent substance use than ACASI. For example, methamphetamine use was reported nearly twice as frequently and alcohol use roughly 14% more frequently via EMA as compared to ACASI. Participants in our

study were not compensated differentially based on their EMA responses; in addition, EMA text exchanges could be expedited by reporting no substance use. Therefore, participants had no material or time-related incentive to over-report their substance use by EMA text. Both ACASI and EMA may minimize concerns related to social desirability bias through the use of electronic, self-administered questionnaires as opposed to in-person interviews [23,24]. However, the frequent, repeated assessments of EMA methods are designed to minimize the duration of participant recall and reliance on autobiographical memory, which can be distorted even after relatively short intervals [6,7]. For these reasons, we hypothesize that daily EMA texting may provide a more accurate and reliable assessment of substance use behaviors compared to questionnaires with longer recall periods, such as the ACASI, or traditional in-person interviews. In addition to potential advantages related to data quality, EMA methods can ease the burden of data collection on study participants by allowing them to report information conveniently and privately during their daily routines and using their own personal devices.

In our multivariable analysis, participants of color were less likely to report concordantly between EMA and ACASI, for both methamphetamine and alcohol use. In prior studies comparing self-reported data to biological tests of substance use, African Americans were more likely to underreport substance use [25-29]. This may be the result of either a lower level of trust and greater reluctance among African Americans to disclose sensitive information to someone of different race, or cultural variations in the interpretation of survey questions [30-32]. African American participants also reported a higher frequency of substance use by EMA text compared to ACASI, suggesting that text-based EMA methods may be more acceptable to this population and may help to mitigate any systematic underreporting among this racial/ethnic subgroup.

We also found that the likelihood of daily concordance was significantly less for days during which participants reported substance use by text. In the case of binge alcohol use, likelihood of daily concordance also decreased as the number of drinks reported by text increased. These findings could be a function of either the acute and residual effects of each substance (as suggested by the association between number of drinks and binge alcohol use reporting concordance) or a greater difficulty in recalling exact temporal details of behaviors that occur more frequently. Although we were not able to assess the validity of our self-reported measures, several studies have demonstrated the validity of EMA reporting in relation to objective biochemical markers of cocaine, tobacco, and alcohol use [17,33,34]. If the EMA-collected data were an accurate representation of substance use behaviors, this finding suggests vulnerabilities with ACASI-collected substance use data in analyses where substance use is the exposure or outcome of interest. In this case, accurate recall and reporting of substance use behaviors would differentially depend on whether or not the participant actually used the substance, which would systematically bias any analytic findings (ie, recall bias) [35].

Limitations

This study has several limitations. First, our small sample size limits both our statistical power to identify significant correlates of daily reporting concordance and our ability to explore differences across a wider array of racial/ethnic groups. Secondly, our convenience sample may not be generalizable to all substance-using MSM. We also had no day-to-day objective measures against which to validate either the EMA or ACASI self-reported measures of substance use; therefore, we cannot make conclusions as to the validity of either method. In addition, daily assessments of the number of drinks consumed in the previous day have been shown to elicit lower reported quantities compared to real-time hourly reporting [36]. Thus, although our assessments are mainly concerned with any substance use on a given day as opposed to the specific quantity consumed, our daily text message measure may be affected by recall bias. Finally, our analyses were restricted to days for which both EMA and ACASI data were available, which may have biased our results if EMA nonresponses or missed ACASI interviews were associated with substance use and likelihood of concordance. Although there were high rates of compliance for ACASI Surveys (95% overall), overall text compliance was modest (68% overall for each substance). An assessment of predictors of EMA text message engagement among the current study sample found that white participants had higher response rates than participants of color, and those who had at least some college education were less likely to stop responding to texts for a prolonged period [37]. This variability in compliance among different demographic groups may further affect the generalizability of the data assessed in this analysis. It is important for future studies to assess the characteristics, concordance, and validity of these data collection methods among samples with elevated reporting compliance.

Conclusions

Our findings have important implications for the collection of self-reported data in substance use research, particularly among MSM. We found that methamphetamine and alcohol use were reported more frequently with daily EMA text compared to retrospective ACASI, concordance varied among different racial/ethnic subgroups and level of education, and reported substance use in EMA text was associated with lower daily concordance with retrospective ACASI. These findings suggest that EMA methods may provide more complete reporting about frequent, discrete behaviors such as substance use, which may be particularly valuable among subgroups more likely to underreport such behaviors.

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Conflicts of Interest

None declared.

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Abbreviations

MSM: men who have sex with men
EMA: ecological momentary assessment
ACASI: audio computer-assisted self-interview
STI: sexually transmitted infection

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Original Paper

Survalytics: An Open-Source Cloud-Integrated Experience Sampling, Survey, and Analytics and Metadata Collection Module for Android Operating System Apps

Vikas O'Reilly-Shah[1], MD, PhD; Sean Mackey[2], MD, PhD

[1]Assistant Professor of Anesthesiology, Emory University and Children's Healthcare of Atlanta, Atlanta, GA, United States

[2]Redlich Professor of Anesthesiology, Perioperative and Pain Medicine, Neurosciences and Neurology, Stanford University, Stanford, CA, United States

Corresponding Author:
Vikas O'Reilly-Shah, MD, PhD
Assistant Professor of Anesthesiology
Emory University and Children's Healthcare of Atlanta
3B South, Room B347
1364 Clifton Road NE
Atlanta, GA, 30322
United States
Phone: 1 615 335 3808
Fax: 1 404 778 0652
Email: voreill@emory.edu

Abstract

Background: We describe here Survalytics, a software module designed to address two broad areas of need. The first area is in the domain of surveys and app analytics: developers of mobile apps in both academic and commercial environments require information about their users, as well as how the apps are being used, to understand who their users are and how to optimally approach app development. The second area of need is in the field of ecological momentary assessment, also referred to as experience sampling: researchers in a wide variety of fields, spanning from the social sciences to psychology to clinical medicine, would like to be able to capture daily or even more frequent data from research subjects while in their natural environment.

Objective: Survalytics is an open-source solution for the collection of survey responses as well as arbitrary analytic metadata from users of Android operating system apps.

Methods: Surveys may be administered in any combination of one-time questions and ongoing questions. The module may be deployed as a stand-alone app for experience sampling purposes or as an add-on to existing apps. The module takes advantage of free-tier NoSQL cloud database management offered by the Amazon Web Services DynamoDB platform to package a secure, flexible, extensible data collection module. DynamoDB is capable of Health Insurance Portability and Accountability Act compliant storage of personal health information.

Results: The provided example app may be used without modification for a basic experience sampling project, and we provide example questions for daily collection of blood glucose data from study subjects.

Conclusions: The module will help researchers in a wide variety of fields rapidly develop tailor-made Android apps for a variety of data collection purposes.

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KEYWORDS

experiential sampling; ecological momentary assessment; quantified self; analytics; Android; Amazon Web Services; DynamoDB; NoSQL; surveys; microsurveys; mobile surveys

Introduction

The explosion of cheap mobile computing technology has led to rapid global adoption of smartphone and tablet technology, with annual smartphone sales accounting for the majority of mobile phones worldwide by 2013 [1]. The Android operating system (OS) is loaded onto more than 75% of these smartphones [1,2]. Accompanying the mobile computing revolution has been the explosion of apps available for mobile OSs, with 1.6 million apps available in Google Play for the Android OS as of July 2015 [3].

The profusion of mobile phones has put vast processing power into the pockets of a large swath of the population. Thus, successful apps with a large number of users may experience commercial success, but also provide an opportunity for studying population-level behavioral dynamics with sample sizes and data precision heretofore impossible to collect.

The corresponding author has written an app, "Anesthesiologist," for the Android OS platform that has experienced a moderate degree of success, with 100,000 users from around the world as of late 2015 [4]. In planning and deploying a research study related to this app, we developed a reusable module for the Android OS that fills 2 broad areas of need.

First, this research study highlighted the need for a tool that allows dual collection of survey data as well as analytics. This allows us to take the analytics data, and behavioral aspects of app use related to these analytics, and parse it on the basis of usage by specific subpopulations. Other developers may be interested in combining analytics with survey data to inform their development cycle. Finally, commercial app developers are particularly interested in characterizing the demographics and usage patterns of their user base for targeted advertising purposes. There are several private commercial solutions that can provide some of the functionality of this module in terms of survey administration [5-8]. However, as mature as some of these products are, none are open source and all are fee-for-service. Moreover, none appear to have the flexibility and extensibility to allow the capture of arbitrary app analytics, requiring 2 vendor solutions to combine analytics with survey administration.

The ability to combine survey and analytic data on a per-user basis is the basis on which investigators can understand how particular subpopulations are using their app. Using "Anesthesiologist" as an example, we know that the app is used by health care practitioners in a wide variety of roles, but we need to use surveys to differentiate the attending anesthesiologist from the junior level trainee. We are also interested in understanding the frequency of app usage, which we can capture using the analytics piece. However, to test the hypothesis that junior level trainees use the app more frequently than attendings, we need to combine this data. The ability to combine analytics with survey data allows investigators to perform a much more nuanced analysis of incoming data.

The second need served by this project is in the area of ecological momentary assessment [9-11], also referred to as experiential sampling. Experience sampling procedures have been used for many years to facilitate the collection of data from subjects during the normal course of their day, as opposed to collection of this data during visits to an office or a lab. This reduces biases in the data related to the need for subjects to remember or aggregate their experiences over a certain interval [12]. These procedures also allow subjects to answer questions within their natural environment as well, perhaps reducing error or bias related to being in the laboratory environment [12]. Quantified-self movement enthusiasts likewise wish to take advantage of modern technology in the pursuit of "self-knowledge through numbers" [13-15].

Several modern experience sampling tools have been developed and released [16-18]. In this arena, mature products have significant costs associated with their use. These include SurveySignal [19], Diario [20], LifeData [21], mEMA [22], iForm [23], movisensXS [24], and iSurvey [25]. Even the relatively mature open-source solutions do not implement enterprise database solutions to provide extensibility, scalability, and security. Paco [26], Aware [27,28], and funf [29] require setup of stand-alone servers, with their attendant information technology (IT) and security concerns as well as the associated cost of hardware and maintenance. Emotion sense [27] and Purple Robot [30] do not offer a storage solution, only export of JSON.

Survalytics represents a substantial improvement over these packages by solving the backend database problem by integrating with Amazon Web Services (AWS) DynamoDB. Amazon Web Services DynamoDB is a hosted NoSQL database service with a flexible data model. For the requirements of Survalytics, minimal database setup is required (described in Multimedia Appendix 1). At the time of writing, AWS offers *indefinite* free-tier service on DynamoDB [31], with 25 GB of free storage and enough free throughput to handle 200 million requests per month. This represents far more capacity than most projects will ever require.

Effective question delivery and response storage is impossible without a solution to this the backend database problem. Compared with stand-alone server solutions, AWS offers intrinsically better security at zero cost, with physical security at the AWS server farms, enterprise-level security architecture and monitoring, active feature development and resource management by AWS, and fine-grained access management options. Amazon Web Services also offers the advantage of virtually guaranteed uptime and extremely low access latency. Survalytics was partially built based on our experience with the development of an unreleased Android port of the Experience Sampling Program, a now antiquated ecological momentary assessment solution built for Palm OS that suffered from many of these problems [12,32].

In short, Survalytics represents a significant leap forward for open-source experience sampling solutions and fills an unmet need in the research community by combining analytics with one-time and ongoing survey question administration on a popular, cheap, widely available OS platform with integration of a cloud-based database service. We expect this combination will fill an important need in the research community by serving

broad swaths of investigators interested in app analytics and administration of one-time surveys to their user base as well as those interested in ecological momentary assessment.

Methods

Software Functionalities

The 3 major functionalities of the module are as follows:

1. Stand-alone app for experience sampling (ongoing questions) and one-time survey administration
2. Add-on module for the administration of surveys to users of existing Android apps
3. Add-on module for the collection of arbitrary data from app interactions or background processes

Software Architecture

We have assembled the basic metadata about Survalytics in Table 1 and listed the required AWS software development kit (SDK) components in Textbox 1. The module is designed as a set of core (Table 2) and supplemental (Table 3) Java classes with minimal user modification required in order for the module to function. These modifications are straightforward and allow the high degree of flexibility for the various applications that this module will likely serve. Figure 1 provides an overview of the life cycle of the module, and Figure 2, Multimedia Appendix 5 provides the details of the interactions between the Java classes. Black arrows signify the calls between classes, and red arrows signify the flow of data into or out of databases. Light green arrows indicate OS-level broadcast events that are received by the module to activate background activity.

In order to get the software compiled and running, the only *required* modification is for users of the module to provide AWS credentials and table data in AWSConstants.java (as public static final variables). Multimedia Appendix 1 provides a walk-through of the process for establishing an AWS account, creating the 2 required DynamoDB tables (for Questions and for Responses), and creating an unauthenticated identity pool with strict security limitations. In particular, this identity pool is strictly limited to reading the Questions table and to writing single responses to the Responses table. Multimedia Appendix 2 provides a walk-through of the process for formatting and inserting questions into the Questions table, and Multimedia Appendix 3 provides a set of sample questions. The schema used is described in Multimedia Appendices 2 and, section I.

Table 1. Code metadata.

Descriptor	Description
Current code version	v1.0
Permanent link to code	http://dx.doi.org/10.15139/S3/12126
Legal Code License	Apache 2.0
Code versioning system used	None
Software code languages, tools, and services used	Java, Amazon Web Services (AWS) DynamoDB, Eclipse Mars IDE[a]
Compilation requirements, operating environments & dependencies	Eclipse Mars IDE Android SDK Target SDK >=9 (GINGERBREAD) AWS SDK for Android
Support email for questions	voreill@emory.edu

[a]IDE: integrated development environment.

Textbox 1. Required Amazon Web Services Android SDK JAR files (tested with version 2.2.5).

aws-android-sdk-cognito-x.x.x.jar

aws-android-sdk-core-x.x.x.jar

aws-android-sdk-ddb-x.x.x.jar

aws-android-sdk-ddb-mapper-x.x.x.jar

Table 2. Core Survalytics Java classes.

Names	Notes
SA_AWSConstants.java	Required modification: AWS[a]credentials
SA_AWSDownloadSurvey.java	Pulls Questions into local DB[a]
SA_ResponseSenderAsynctaskService.java	Packages Responses and stores in local DB for later upload
SA_AWSInsertStudyJSON.java	Pushes Responses to AWS
SA_DisplaySurveyQuestion.java	Displays Questions
SA_QuestionDB.java	Wrapper class for all local DB calls
SA_Question.java	AWS DynamoDB Annotated Question object
SA_Response.java	AWS DynamoDB Annotated Response object
SA_AWSSurveyConnectivityBroadcastReceiver.java	Background Question download and Response upload with connectivity change

[a]AWS: Amazon Web Services; DB: database.

Table 3. Supplemental Survalytics Java classes.

Names	Notes
SA_AWSQuestionVerificationAndDisplay.java	Question Display and Validation Should not be included in production release of application
SA_NotificationAutomaticity.java SA_NotificationGroupNotifier.java SA_NotificationSetter.java	Survalytics Sampling: add-on classes for ecological momentary assessment (experiential sampling)

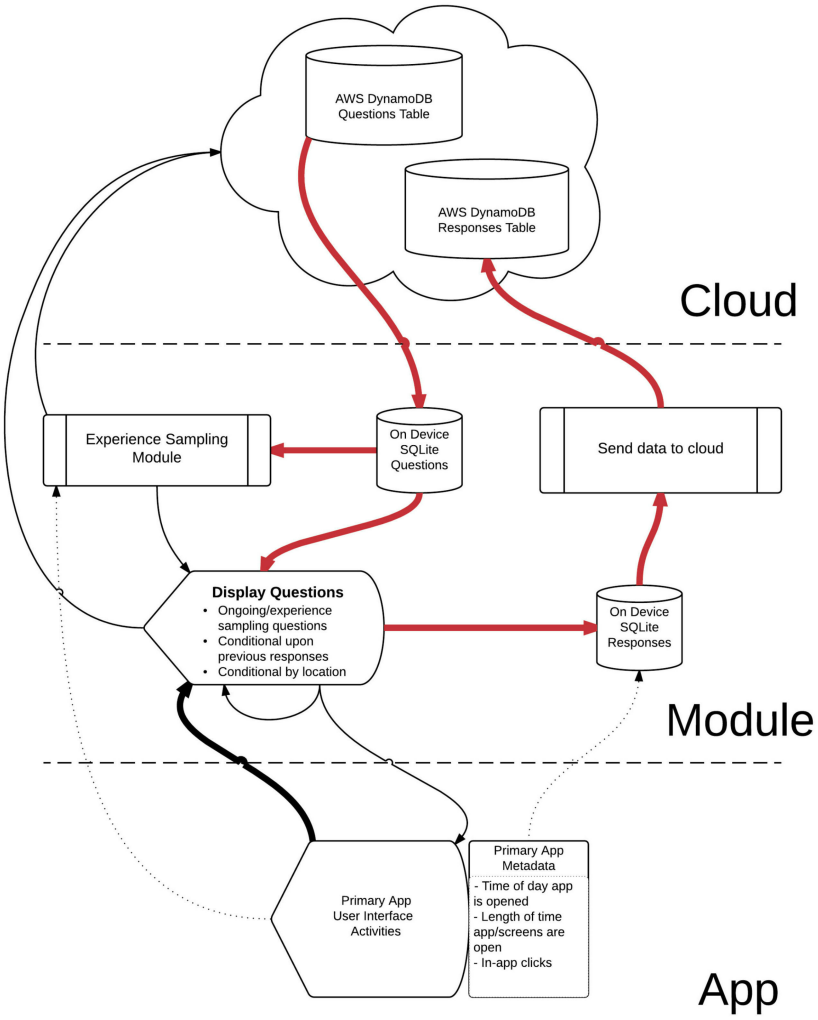
Only 1 of the core classes—DisplaySurveyQuestion—must be called by the end user to achieve survey functionality (dark arrow from the main user interface (UI) activity). All of the other classes provide background functionality for the module. DisplaySurveyQuestion is an Activity that displays questions present in the local database and also initiates a download of questions (red data flow arrow) from the cloud AWS table if no new questions are available. The activity recursively cycles through unanswered questions until no relevant questions remain. The end user has the option to delay answering questions until later ("Not now/answer later" button, easily removed from the UI if investigators do not wish participants to be able to delay answering).

In terms of analytics, as indicated in Figure 1 by dotted lines, users of the module may also optionally store additional types of data such as UI clicks, user inputted data, app metadata, or otherwise processed data using a direct call to ResponseSenderAsyncTaskService. The Responses class should be modified under these circumstances. In the study of the "Anesthesiologist" app mentioned in the Introduction section, we use this analytics storage component to track a variety of app uses, including total time using the app (per launch) and a variety of in-app clicks. This allows fine-grained analysis of the app usage linked directly to the survey responses collected, as described above, using DisplaySurveyQuestion.

Whether storing survey or analytics data, the data are stored on-device before attempting upload. If the device is offline, data are persisted in a private SQLite database on-device until the device comes online. The Android OS security model prevents access to these private SQLite databases by other apps and is only otherwise accessible by physically connecting a rooted, unlocked Android device to a computer. The change in connectivity is detected by the package (Figure 2, Multimedia Appendix 5) and upload of all stored data is initiated at that time.

Multimedia Appendix 4 contains the full JSON schema for the app and AWS tables and demonstrates the modifications to Responses required in Section IV. However, it should be noted that all data packaged into JSON for upload are transmitted to the final AWS Responses table in the "json_str" field. Therefore, even without modification to Responses, the data will remain preserved. This comes at the price of doubling the stored data; because storage is cheap and data are precious, this prevents situations where incorrect modification of Responses leads to loss of data. In this situation, users of the module will need to extract the JSON from the AWS Responses table to get at the data. Eventually, the AWS SDK for Android will likely include functionality to allow insertion of arbitrary JSON directly into DynamoDB tables, already a feature of the AWS SDK for Java [33]. This should obviate the need for Responses and for preventative double storage.

Figure 1. Overview of the Survalytics platform architecture. Black arrows are calls between subclasses of the module. Red arrows demonstrate data flow. Dotted lines serve to clarify the functionality and data storage existing in the original app, in the Survalytics module, and in the cloud database. The software module may be called by the primary app in several different ways. For surveys, the app should send a call to display survey questions. The app may make a different call to store arbitrary analytic data in the cloud. Finally, if desired, the app can call the experience sampling submodule. AWS: Amazon Web Services.



Illustrative Example

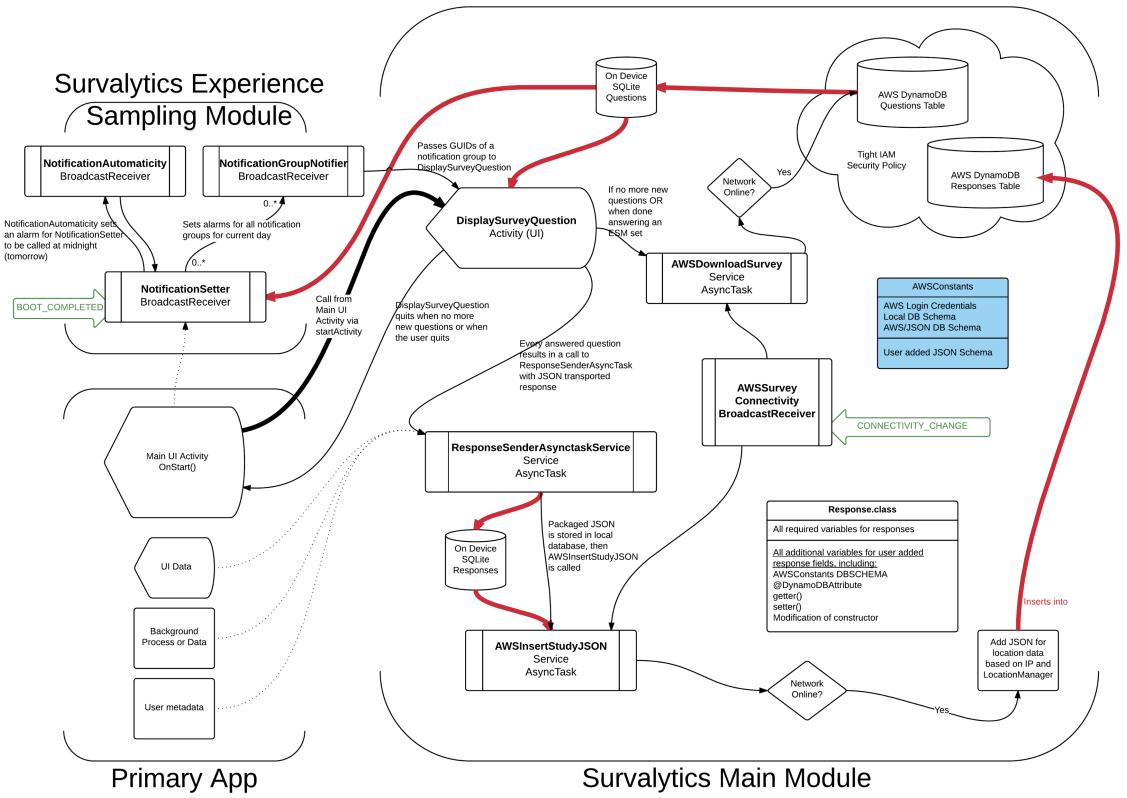
Users may follow one of the many available guides for the setup of an Android integrated development environment (IDE) [34,35]. Survalytics was coded and tested using the Eclipse IDE [36]. Android Studio [37] is an IDE provided by Google for Android development, and the use of the module in that environment may require modifications to the module other than those described in the Multimedia Appendix 4.

After setting up the AWS DynamoDB tables as outlined in Multimedia Appendix 1 and inserting questions into the Questions table as outlined in Multimedia Appendix 2, the project should be loaded into the selected development environment and modifications made to AWSConstants.java to include the AWS security credentials gathered in Multimedia Appendix 1. The package also relies on the Android SDK for AWS [37,38]. Once downloaded, the 4 required Java Archive (JAR) files in Textbox 1 should be copied into the *libs* folder of the project. At this point, the project may be compiled and deployed onto a test or emulated device.

Important permissions and declarations are included in the Android manifest file and should be made note of when using Survalytics as an add-on module. These include permissions for Internet connectivity and use of the Global Positioning System and declarations for all the Survalytics classes. Any projects making use of the Survalytics must include these permissions and declarations in the Android manifest for proper functionality.

The package may be tested using the questions provided in Multimedia Appendix 3, modeled on the types of questions that might be asked in a study of blood glucose monitoring in diabetic patients. The Survalytics Question Builder for Google Sheets provides a simple template that will take the desired values for *questionguid_str*, *ordinalposition_int*, and so on and export JSON for easy insertion into the AWS Questions table. Users may validate the insertion of questions in the AWS Questions table using AWSQuestionVerificationAndDisplay, as discussed below.

Figure 2. Detailed Survalytics platform architecture. The calls to be made from the primary app to the specific Java classes of the module are detailed here. In addition, the internal relationships between the classes of the module are also detailed. Black arrows are calls and red arrows demonstrate data flow. Light green arrows represent system level events that drive calls to the indicated classes. AWS: Amazon Web Services; DB: database; ESM: experience sampling module; IAM: Identity and Access Management; IP: Internet protocol address; JSON: JavaScript object notation; SQL: structured query language; UI: user interface. See Multimedia Appendix 5.



The example app and questions provide insight into how the various functionalities of the module may be tied together to create a comprehensive study framework. Upon loading, an AlertDialog requesting consent for participation in the study is displayed. Acceptance or rejection of consent is uploaded to the AWS Responses table with entrytype “consentcode.” This is an example of direct upload of app UI data. Questions 10-40 are questions that are asked only once and collect basic demographic information about the study patients and their diabetes management. Question 100 is an ongoing experience sampling question asked daily at 11 am and 6 pm. Questions 101 and 110 illustrate the deletion of ongoing question 100 and insertion of the same ongoing question, except asked daily at 7 pm and then at 12 noon on Sunday only. Question 50 illustrates the use of *delaybydays* while question 60 illustrates the use of *conditional-upon-questionguid* and *conditional-upon-responseid*. The question will only be asked if question 40 (*questionguid* “DM1-FOLLOWUP”) was answered with *responseid* 1 (“Monthly”). Questions may also be *conditionalbycountry* ; this should be a comma-delimited list of International Organization for Standardization 3166 alpha-2 country codes listing the countries in which the question should be asked.

A basic survey visualization tool is included with Survalytics. This is the AWSQuestionVerificationAndDisplay class. As demonstrated in the example app, we recommend including this class as a menu option during survey development and app testing. This class presents the entire survey present in the AWS Questions table for inspection. While processing the questions, it performs a series of validation checks, including uniqueness of *ordinalposition*, validity of *conditional-upon-guid* and each *conditional-upon-responseid*, validity of each *notificationtime*, and validity of *deletequestion*. All elements of the question, including conditionals by time or country, are displayed. In the case where questions are *conditional-upon-guid*, each of the *conditional-upon-responseid* is matched to the *responseid_int* of the original question and those *response_str* are displayed, allowing at a glance verification of branch points. The menu option and the class itself should be removed from the production version of the app.

Discussion

As indicated in the Introduction section, this project was motivated by the need for a tool with broad functionality allowing data capture across several domains. The flexible data

model offered by NoSQL database solutions simplifies the approach to database management and data capture. By combining survey data with in-app usage analytics, we can capture detailed usage patterns of mobile Android apps and parse that behavior based on the collected demographics. As mentioned, the module will be deployed as part of a large research study of an international population of anesthesia providers. This study may shed important light on global practice patterns and areas for practice improvement in the global or in targeted communities. Most intriguingly, the module can serve not just to ask questions but also to deliver payloads of educational content to targeted end users based conditionally on their responses, location, and so on.

The stand-alone experience sampling functionality fills a substantial need in that it is the first cloud-integrated open-source experience sampling program available for deployment on a modern smartphone platform. The uses of such a program span a wide variety of fields, from sociology to economics to psychology to the biomedical sciences. As mentioned, existing solutions either are expensive and closed-source or lack the broad functionality presented here. The previous unreleased port of the Experience Sampling Program (ESP) to Android, presented in a poster session to the American Society of Anesthesiologists, generated several unsolicited requests from interested research groups. Survalytics should be a welcome addition to the experience sampling community.

One major advantage of Survalytics over existing packages is the use of AWS free-tier offerings. Amazon Web Services has a comprehensive security model (termed Identity and Access Management, or IAM), allowing extremely fine-grained permissions to be granted to various users. For example, users can have limited read and write capabilities down to the table level. Data security was a prime consideration in choosing AWS over other possible solutions; stand-alone servers may go without security updates in the absence of a mature IT support framework, and the other major NoSQL platform, MongoDB, offered very little in the way of granular security. Survalytics uses so-called "unauthorized entities" to access questions and write responses, but these "unauth identities" cannot write to the questions table or read the responses table if set up according to the instructions in Multimedia Appendix 1. All communication using the AWS SDK is, by default, secure sockets layer (SSL) encrypted. Access to data is limited by the account holder, and secondary users may be defined by that account holder using IAM with limited permissions. Certain AWS services are designed with Health Insurance Portability and Accountability Act (HIPAA) and personally identifiable information (PII) compliance in mind; DynamoDB is one of them. Interested parties may execute business associate agreements with AWS to use their services in a HIPAA compliant manner [39].

Using AWS carries some other significant advantages. There are mature SDKs available for a variety of platforms, including iOS, opening the possibility of developing Survalytics for other platforms (discussed below). Amazon Web Services offers a number of other free or low-cost services that may eventually be integrated into the Survalytics platform, including cloud computing and long-term archival services.

Although the Survalytics package as offered provides all the essential tools required to deploy the functionalities provided, several avenues of development remain. A data exploration tool for basic exploratory data analysis and visualization of the AWS Responses table would be valuable, in particular for users with a substantial analytics component or for those users collecting large datasets. Additionally, a more integrated approach to question building and upload may be helpful for those working with large surveys or multiple survey sets. The on-device language is currently detected by Survalytics, but there is no current mechanism to localize delivered questions on the basis of this language. This would be straightforward to implement but not a current area of need.

A major area of development is to port Survalytics to the iOS platform. We initially focused on developing the platform for Android OS as Android devices are profoundly cheaper than iOS devices, allowing researchers to deploy Survalytics at much lower equipment costs. While iOS devices have a higher market share in developed countries, Android continues to maintain parity with iOS globally. Our planned deployment of Survalytics for study of the "Anesthesiologist" app, currently only available for Android, led us to initially focus on the Android OS version of Survalytics. We are also actively exploring development of a cross-platform version of Survalytics using Xamarin.

Hopefully, contributions in some of these areas will emerge from the open-source user community, although development of tools for the projects we currently have in progress will only serve to further develop the Survalytics package for all users. Exploratory data analysis using the open-source statistical package R [40] is straightforward to implement using the jsonlite [41] library for import.

Efforts were made to optimize the end-user experience while maximizing code efficiency, but the user interface, which relies on the basic set of views and components provided by the Android OS, may be improved upon by contributors with experience and expertise in UI. There are almost certainly areas where the codebase could be optimized to reduce resource utilization or increase speed. On the other hand, the code was written explicitly adopting a philosophy in which simplicity of codebase took precedence over bandwidth or storage considerations. Since the module is targeted for use by nonexperts and experts alike, this approach improved the readability of the code. This accessibility should result in a larger number of researchers adopting the package as well as contributing to its further development.

Acknowledgments

We would like to thank Jose Pons Vega for contributions during the development of the initial port of the Experience Sampling Program in 2011.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Amazon Web Services walk-through.

[PDF File (Adobe PDF File), 1MB - mhealth_v4i2e46_app1.pdf]

Multimedia Appendix 2

Question formatting and insertion.

[PDF File (Adobe PDF File), 43KB - mhealth_v4i2e46_app2.pdf]

Multimedia Appendix 3

Sample questions table.

[XLSX File (Microsoft Excel File), 57KB - mhealth_v4i2e46_app3.xlsx]

Multimedia Appendix 4

JSON and database schema.

[PDF File (Adobe PDF File), 66KB - mhealth_v4i2e46_app4.pdf]

Multimedia Appendix 5

Detailed Survalytics platform architecture.

[PNG File, 876KB - mhealth_v4i2e46_app5.png]

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Abbreviations

AWS: Amazon Web Services

HIPAA: Health Insurance Portability and Accountability Act
IT: information technology
JAR: Java Archive
OS: operating system
UI: user interface

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Original Paper

User Perceptions of ¡Protéjase!: An Intervention Designed to Increase Protective Equipment Use Among Mexican Immigrant and Mexican American Farmworkers

Shedra A Snipes[1], Ph. D; Francisco A Montiel-Ishino[1], MPH; Joshua M Smyth[1], PhD; Dennis J Murphy[2], Ph. D; Patricia Y Miranda[3], Ph. D; Lisa A Davis[4], MHA

[1]Penn State University, Department of Biobehavioral Health, University Park, PA, United States

[2]Penn State University, Department of Agricultural and Biological Engineering, University Park, PA, United States

[3]Penn State University, Department of Health Policy, University Park, PA, United States

[4]Pennsylvania Office of Rural Health, University Park, PA, United States

Corresponding Author:
Shedra A Snipes, Ph. D
Penn State University
Department of Biobehavioral Health
125 Biobehavioral Health Building
University Park, PA,
United States
Phone: 1 814 865 4668
Fax: 1 814 863 7525
Email: sas84@psu.edu

Abstract

Background: Farmworkers' exposures to pesticides are reduced when they wear personal protective equipment (PPE), and mobile health (mHealth) platforms can potentially deliver information to farmworkers to help promote PPE use. However, little is known about the feasibility of using mHealth platforms to promote farmworkers' use of PPE.

Objective: The objective of the study was to describe the development and feasibility-testing of Protect Yourself! (¡Protéjase!), an intervention designed to increase PPE use. As the vast majority of farmworkers in the United States are from Mexico, we examined the intervention in a primarily Mexican-origin farmworker population.

Methods: ¡Protéjase was developed in several steps. First, we performed ethnographic observations to understand what prevents PPE use. Next, we developed program components that met the challenges uncovered in the ethnographic observations, seeking direct feedback from farmworkers on each component. Feasibility was assessed using surveys and focus groups. Material was provided in Spanish or English at the preference of the participant. Finally, we pilot tested each component of the intervention, including: (1) PPE that was provided to each worker for their personal use during the intervention trial, and (2) delivery of an application-based tool that promoted the use of PPE through daily individualized messaging.

Results: 55 farmworkers enrolled in the study, but only 41 of 55 (75%) completed the entire pilot intervention trial. Results focus on the evaluation of the intervention, and include only those who completed the entire trial. Among farmworkers who completed the entire intervention trial, all but two farmworkers were born in Mexico and were Spanish speaking. Still, all study participants self-identified as Mexican or Mexican-American. When asked what changes were needed in the intervention's messaging or delivery to increase user satisfaction, 22 out of 41 participants (54%) felt that no changes were needed. However, 16 of 41 participants (39%) suggested small changes to messaging (eg, refer to long pants as pants only) to improve their understanding of the messages. Finally, a small number (3 of 41 participants, 7%) felt that messages were difficult to read, primarily due to low literacy.

Conclusions: The ¡Protéjase! mHealth program demonstrated very good feasibility, satisfaction, and acceptance; potential improvements (eg, small modifications in messaging to increase farmworkers' use) were noted. Overall, the PPE provided to workers as well as the mHealth platform were both perceived as useful for promoting PPE use.

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KEYWORDS

mHealth; Hispanic; migrant worker; intervention study; pesticides; occupational safety

Introduction

The use of personal protective equipment (PPE) significantly reduces workers' exposures to pesticides [1-5]. Further, PPE is recommended by the Environmental Protection Agency as the primary way to protect farmworkers who may be exposed to pesticides as they work [6]. However, exposure to pesticides among farmworkers is not equal. Over 80% of the agricultural workforce is of Mexican origin [7], and recent research indicates that farmworkers who identify as Latino have significantly greater exposures to pesticides [8]. It is critical, then, to develop new venues for interventions that can help promote pesticide safety for Mexican and Latino farmworkers.

Intervention strategies such as the use of mHealth (broadly defined as the use of mobile and wireless devices to improve health, health services, and health research) present a unique and viable intervention platform to improve PPE use. Moreover, there is preliminary evidence that Mexican and Latino farmworkers are likely to have mobile phones and are willing to receive health information in a mHealth format [9-11]. However, utilizing a mHealth approach for pesticide safety among a Mexican farmworker population has not yet been explored. As such, we developed and implemented a mHealth intervention named Protect Yourself! (¡Protéjase!), which was both broadly (eg, language, culturally appropriate) and dynamically (daily risk profiles) tailored to promote PPE use among Mexican farmworkers. Our efforts build on the growing use of mHealth as an approach to capture daily data to implement messaging based on individual-level characteristics, such as changes in daily risk factors [12]. Specifically, our objective was to pilot test each component of the intervention, including: (1) provision of PPE (long-sleeved shirts, gloves, and safety glasses) that was provided to each worker for their personal use during the intervention trial and (2) delivery of an application (app)-based tool that promoted the use of PPE through daily individualized messaging.

Methods

The Steps of ¡Protéjase! Intervention

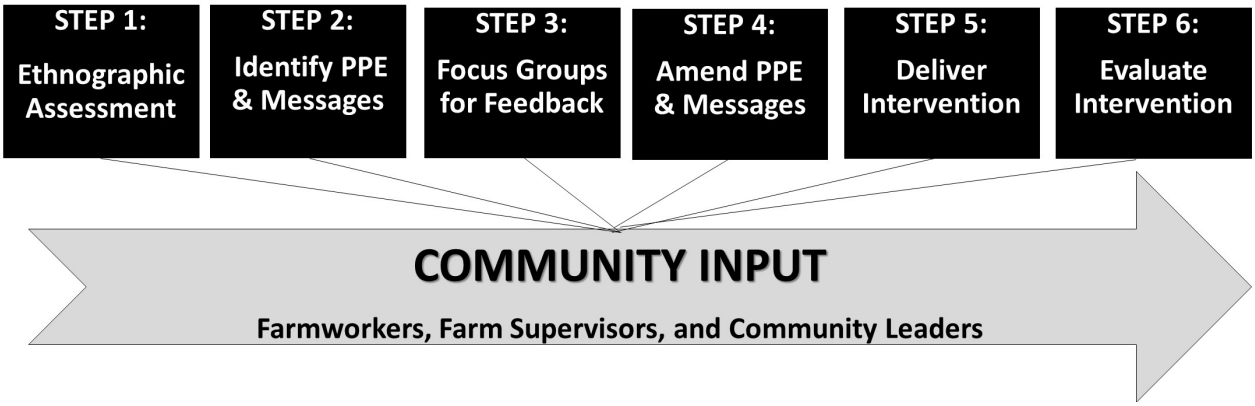
Step 1

The ¡Protéjase! intervention was developed in six steps (Figure 1 shows this). Step 1 entailed a series of ethnographic assessments performed by the primary investigator. The overall goal of ethnographic assessments was to better understand why workers did not wear their PPE, or removed it (eg, because it interrupted or slowed their work). Data for the ethnographic components were collected during 3 periods: 3 months of spring evaluation (April 2009 to June 2009), 10 months of winter and spring evaluation (October 2009 to July 2010), and 3 months of summer evaluation (June 2011 to August 2011). The participant samples were 32, 30, and 35 respectively. Participants for the ethnographic studies were all recruited through parent meetings at Teaching and Mentoring Communities, Inc (TMC), a nonprofit organization with a Migrant and Seasonal Head Start program that serves approximately 8000 children of parents who work in agriculture. TMC is located in the Lower Rio Grande region of Texas where a significant portion of residents are farmworkers [13].

Ethnographic observations of PPE use behaviors typically took between 6-9 hours, and occurred 5-7 days per week for a total of 3387 observational hours. Additional time in the field included transcribing notes, which were captured using a digital voice recorder and written in a notebook using a shorthand system that allowed the investigator to quickly record observations. Also, 74 interviews were conducted that inquired about reasons behind PPE use/nonuse, ranging from 30 minutes to 3 hours each. Finally, between 2-5 hours of every observation day was used writing field diary notes, coding notes, listening to voice recordings of interviews, and keeping an active field diary. The relevant Institutional Review Boards (2009-2010 by MD Anderson Cancer Center; 2011 by the Pennsylvania State University) approved all work for the ethnographic studies.

The ethnography produced numerous examples of why farmworkers removed their PPE, or did not put it on at all. For example, previous work has described that farmworkers' beliefs about individual vulnerability and machismo may influence pesticide exposures [14-16]. Building upon that literature, our observations showed that someone who self-perceives their body as "delicate" or "weak" in their organismo (body-type) might more readily wear their PPE. In fact, workers described as delicados (persons with a delicate body type) were encouraged by their family or coworkers to put on PPE even if it slowed them down. On the other hand, we found that PPE is strongly perceived as a barrier to efficient work, and is seen as preventing most workers from achieving important harvest quotas (which, when not met, may result in loss of pay or employment). Thus, workers who had a stronger "organismo" were less likely to wear PPE because their body type was perceived as strong enough to forgo PPE use, and because PPE decreased their work efficiency.

Figure 1. ¡Protéjase! development steps. Personal protective equipment: PPE.



Step 2

Next, in step 2, we began to develop program components that met the challenges uncovered in the ethnographic observations. First, we sought PPE that would be perceived as practical enough to not impede productivity. Further, we aimed to establish messages designed to address key barriers for the use of PPE, thus enhancing motivation for and execution of or execution of PPE. To do this, we first identified multiple options of each type of PPE (ie, long sleeved shirts, safety glasses, and gloves) that could be worn comfortably throughout the workday. PPE was located by contacting occupational equipment companies whose products were a potential match for the criteria of functional wear without impeding work productivity. Criterion factors included fabric with heat cooling technology, nonfog lenses, and gloves that promoted maximum dexterity. In total, we were able to identify 22 options, which included 4 types of shirts, 10 types of gloves, and 8 types of safety glasses. Next, culturally appropriate messages were drafted. To create messages, we used a matrix-based guiding framework from Intervention Mapping [17]. Message development started with a matrix that placed behavioral objectives in rows, which included goals such as putting on a long-sleeved shirt and keeping the long-sleeved shirt on all day. Determinants that influenced the goals were placed in columns, and included perceived barriers, perceived benefits, self-efficacy, knowledge, and attitude (among others). In a row-by-row fashion, we created multiple corresponding messages for each cell in the matrix attempting to minimize repetitiveness (resulting in a total of 309 messages). Also, the wording of each message considered that delivery was to take place in an individually tailored manner, and in direct response to their actual daily behavior. For example, a sample message was: “We know - sometimes it’s hard to wear protective clothing. Today you did not wear your gloves because they were uncomfortable. However, we want you to know that pesticides can be harmful when you are exposed to them. In order to protect yourself, wear the appropriate protective clothing every day”.

Step 3

In step 3, we conducted 5 focus groups among 50 adult farmworkers (10 farmworkers per focus group) to gain their opinions on both the PPE and draft messages developed in step 2. Focus groups were approved by the Institutional Review Board at Penn State University, and held at the TMC facilities. We recruited 50 farmworkers by attending parent meetings at TMC. Among the 50 focus group participants, they provided feedback on types of PPE, which were evaluated by farmworkers for both comfort and productivity (uncomfortable/slows productivity, comfortable/slows productivity, helps productivity/uncomfortable, helps productivity/comfortable). Additionally, intervention messages were discussed and evaluated, and then group-ranked according to their potential impact to motivate increased PPE use.

Step 4

In step 4, we reviewed farmworkers’ feedback on PPE and messages. First, based upon farmworkers’ suggestions, PPE was narrowed from 22 to 7 types that farmworkers perceived could be feasibly worn throughout the workday (1 shirt, 3 types of gloves, and 2 types of safety glasses). We kept PPE according to farmworker’s rankings of highest level of protection in conjunction with their most pragmatic needs (ie, comfort and productivity). Representative quotes of farmworker’s perceptions of highly evaluated PPE are available in Table 1. Next, the draft messages were evaluated. Based on farmworker’s feedback, messages were narrowed from 309 messages to 209 messages. Most messages were removed because farmworkers viewed them as too lengthy, or not convincing enough to motivate PPE use. A small number of messages were removed because they repeated the overall goal of other messages. The top-rated PPE and edited messages were integrated into the intervention design.

Table 1. Representative quotes regarding perceptions of highly evaluated PPE.

PPE	Farmworker quotes
Gloves	"These gloves fit better and are more comfortable, they would be good for jobs that require handling small fruit picking."
	"These gloves are perfect for working with tasks that require good grip while handling sharp plants or knives."
Long sleeve shirt	"This shirt is good for work because it protects you all the way to the wrist, it looks comfortable, it looks like a dress shirt, you can put your pen, and small tools in the pockets."
Glasses	"These glasses are great for when we bend down. You can use them with the straps too so they don't fall off while you are working."
	"These glasses are good for when you are driving a machine."

Step 5

Next, in step 5, we pilot tested the intervention in a new sample of 55 farmworkers (no farmworkers from the focus groups participated in the pilot delivery trial). The Institutional Review Board at Penn State University approved all pilot study components. Program participants were recruited from TMC through parent meetings, and written informed consent was obtained in Spanish or English, depending on participant preference. In order to ensure consistency in the function of the pilot mHealth app, and to standardize presentation of materials (eg, screen size, power, maintenance, etc), farmworkers were provided with mobile phones, instruction on basic phone use (eg, how to turn the phones on-off), and trouble-shooting of technical issues (ie, how to deal with frozen screens) prior to starting the pilot intervention. Participants were then taught how to use the ¡Protejase! mHealth app, including how to respond to daily surveys. Farmworkers were also provided the optimized PPE (long-sleeved shirts, gloves, and safety glasses). Additional training was provided to farmworkers on the correct use of PPE with tips for increased comfort and wear while working in the fields. Each training session took approximately 45 minutes. Finally, a toll free number with 24-hour accessibility to project staff was provided to participants to call if they had questions or issues with mobile phones or PPE for the duration of the study. Participants were given a US $15 participant Wal-Mart gift card and were able to keep the PPE after the pilot study concluded.

To deliver individually and dynamically tailored messages to each person in the pilot study, a short daily survey was delivered via the ¡Protejase! mHealth app at the end of each work day. The survey assessed information for that current day, including work hours, the type of work performed, the type of crop harvested, pesticide application, PPE use, reasons why PPE was worn (or not, tailored to responses), and farmworkers' perceptions of work safety. After completing the survey, farmworkers received an individually tailored message based on their responses to the survey for that day. As alluded to earlier, messages were designed to be responsive to all possible combinations of PPE use scenarios, risk beliefs, and work tasks. To accomplish this without becoming repetitive (particularly in the context of repeated PPE failures in the same domain), the app contained 5 different messages per potential scenario to prevent the same message being delivered if participants engaged in the same behaviors for more than one day (messages could, however, repeat after 5 instances). As an example of message tailoring, if a participant indicated that protective gloves were not worn, they were prompted to provide the reason the PPE was not worn (eg, forgot to wear them, too hot, uncomfortable, slowed productivity, etc). We also assessed any perceived difficulties or negative consequences of wearing PPE, if worn. When participants indicated, for example, that they did wear gloves that day, they were prompted to "Please let us know if you experienced any of the following challenges while wearing your gloves today" and could indicate if glove use slowed productivity, was too hot, uncomfortable, etc. Answers to the completed survey were then assembled and matched to a motivational cue specifically tailored to remind the participant to wear the appropriate type of PPE (in this example, gloves) the following day. Motivational messages were provided on a daily basis, and included reminders to wear PPE, information about the health risks of pesticides, and helpful tips to use PPE effectively to remain safe at work (Figure 2 shows an example). The pilot test was implemented daily over a 30-day period.

Figure 2. Dynamically tailored ÃƒÆ'Ã†â€™ÃƒÂ¢Ã¢â€šÂ¬Ã…¡Ã‚Â¡ÃƒÆ'Ã¢â‚¬Å¡Ã‚Â¡ProtÃƒÆ'Ã†â€™Ã‚Â¡ Ã¢â‚¬Å¡Ã„Ã¢â€šÃ‚Â¡jase! daily survey example.

Step 6

Finally, we evaluated the feasibility and preliminary effectiveness of ¡Protejase! in step 6. To evaluate the intervention, baseline and follow-up surveys were used to assess feasibility characteristics as well as change in PPE use in response to the intervention trial. Feasibility assessment included perceived barriers to PPE use, loss to follow-up, comprehension of mHealth messages, survey and message delivery time and frequency of messages, ease or difficulty of mobile phone use, battery life, and phone screen issues (such as freezing and font size). Additionally, all participants who completed the entire 30-day intervention participated in one focus group at the close of the intervention to provide open feedback on the intervention feasibility.

The Analysis

For analyses, basic descriptive statistics assessed average percentages and ranges. Additionally, Pearson's linear correlations and simple linear regression were used to understand relationships between barriers in mobile phone use and mHealth assessment since the intervention. Linear associations were analyzed controlling for potential influence of income, education, and mobile phone ownership as each could affect barriers to mobile phone use among participants. For qualitative analyses of the evaluation focus groups, data were coded by two independent coders and underwent thematic content analysis. Coding and analysis was iterative, and themes were derived by frequency of codes (most occurring concepts), repetition of perceptions across subjects and groups, and consensus of perception by farmworkers' demographic attributes. To assess concepts across groups and attributes, codes were linked and explored for patterns based on demographic profiles to compare and identify common themes among participants.

Results

Intervention Enrollment

A total of 55 farmworkers were enrolled and began the intervention trial, with 41 (75%) completing the 30-day study. Evaluation of the intervention is based on the sample (n=41) that completed the trial and were available at follow-up. Participant characteristics at baseline and follow-up are included in Table 2.

Farmworker Mobile Phone Use

All participants identified as Mexican or Mexican-American. There was high preexisting mobile phone use in this population both in the enrollment sample, and in the sample that completed the entire intervention trial. Among farmworkers who owned

a mobile phone, (n=14/34) 41% indicated using it on a regular basis for phone calls to-and-from family and friends.

Table 2. Demographic profile of ¡Protéjase! feasibility study participants at baseline (n=55) and follow-up (n=41).

		Baseline		Follow-up	
		n	%	n	%
Language					
	Spanish	52/55	95	39/41	95
	English	3/55	5	2/41	5
Sex					
	Male	31/55	56	23/41	56
	Female	24/55	44	18/41	44
Place of birth					
	Mexico	48/55	87	39/41	95
	United States	7/55	13	2/41	5
Age					
	< 20	3/55	5	1/41	2
	21–30	28/55	51	22/41	54
	31–40	14/55	26	11/41	27
	41 +	8/55	15	6/41	15
	Don’t know/refused	2/55	3	1/41	2
Education completed					
	< 8^{th} grade	24/55	44	17/41	42
	9^{th} -11^{th} grade	13/55	24	10/41	24
	12^{th} grade or GED	12/55	22	10/41	24
	Some college baccalaureate	3/55	5	2/41	5
	Don’t know	3/55	5	2/41	5
Annual Income (US)					
	< $10,000	28/55	51	21/41	51
	$10,000-$14,999	10/55	18	8/41	20
	$15,000-$24,999	5/55	9	3/41	7
	Don’t know	12/55	22	9/41	22
Owned a mobile phone for personal use					
	Yes	41/55	75	34/41	83
	No	13/55	24	6/41	15
	Don’t know	1/55	1	1/41	2
Mobile phone use (among those who own a mobile phone)					
	Always	10/41	24	9/34	26
	Sometimes	6/41	15	5/34	15
	Hardly	25/41	61	20/34	59

Personal Protective Equipment Satisfaction and Acceptability

The overwhelming majority of participants were pleased with the PPE and mHealth messages. The long-sleeved shirts were described as “...good, [well] ventilated and fresh (...estaba bien, tenia ventilacion, estaba fresca)” because it “kept [them] dry and free from sweat (...mantenia seco...sin sudor)”. Safety glasses were seen as a welcome addition as they were provided in various tints, “were ventilated (estaban ventilados)” and did

not “fog”. Gloves were generally liked because, in addition to protecting hands, they “limited rashes” among harvesters.

A small number of barriers were reported that limited practical PPE use. In the case of long-sleeved shirts, issues were only related to sizing. A participant reported “[their] shirt was very large [and] uncomfortable [because] the sleeves would get stuck and become bothersome (la camisa estaba muy larga...[y] era incomoda[...]se atoraba[...]y estorbaban las mangas)”. Other barriers to PPE use were crop specific to cilantro harvesting, which required the modification of gloves to allow bunching and tying of the crop. A participant expressed this sentiment noting, “gloves did not work well for cilantro...they only work well for certain tasks (los guantes no[...]sirvieron mucho...[son buenos para ciertas cosas])”. To deal with the practical issues of glove use with cilantro, participants often modified gloves by cutting off the tips on the thumbs and index and middle fingers, giving them the dexterity they needed to bunch and tie the crop in the field, while maintaining some (more limited) degree of protection. It should be noted that participants indicated that prior to the intervention, they did not wear gloves at all while harvesting cilantro, but wore them in a modified way after provision by the ¡Protéjase! program.

An additional barrier with the gloves was that they had high turnover dependent on the speed and output of the harvester. Participants also commented that they might need more than 2 pairs of each glove over the 30 day timeframe (the average observed turnover of gloves among all farmworkers was 2 weeks for each pair, suggesting our provision of 2 pairs was a roughly adequate timeframe for the length of the study period). Despite the barriers, participants expressed that PPE was beneficial and important overall.

mHealth Satisfaction and Acceptability

The daily survey and PPE motivational messages were also well regarded, as indicated by one participant who stated: “the questions were easy (las preguntas estaban fáciles)” and “[my] favorite [part] was the messages ([mi parte] favorita fueron los mensajes)”. According to participants (see Table 3), the most useful messages were about the health effects of pesticides and risk to their family (collectively selected as most useful by 27/41; 66%) and tips and reminders on PPE use (13/41; 32%). When asked about possible message changes, many participants (22/41; 54%) liked all risk-reduction messages and felt that no changes were needed; (n=16/41) 39% liked the messages, but felt that some refinement (such as small changes in language) was needed to most effectively increase PPE use. As an example of a suggested change, participants found use of the term “long pants” confusing and suggested just referring to them as “pants” only. Finally, (3/41) 7% felt that messages were difficult to read, which appeared to primarily reflect low literacy levels of some participants. We also established in focus group discussions that some participants (7/41; 17%) had trouble navigating the mobile phones due to literacy issues. In those cases, five spouses/wives and two children helped participants complete the daily survey. Each of the seven participants who reported literacy issues in the focus groups said that they were able to successfully complete the survey each day in one sitting because of the help of a family member or spouse to read the daily survey and messages. See Table 3 for a detailed breakdown on mHealth message satisfaction.

Barriers to Mobile Phone Use

The primary perceived barrier to the mHealth approach was difficulty with technical issues regarding the mobile phone (such as battery life or freezing of the phone’s screen). The majority of participants (30/41; 74%) indicated they had no barriers using the mobile phone and reported the questions as “being easy (estaban fáciles)”. Of the approximately (11/41) 27% of participants who reported barriers, these barriers appeared related to technological challenges in accessing the survey on the phone. Despite any such barriers, provision of daily surveys was quite good. Overall, 786/959 (81.9%) surveys were successfully completed in one attempt, an additional 148/959 (15.4%) surveys in two attempts, and a small fraction requiring three or more attempts (25/959; 2.6%).

Our data also show that the average length of time required to complete the daily survey was moderately associated with perceived barriers of mobile phone use [r= 0.355; P=.025], suggesting that participants who reported barriers were more likely to take longer to complete daily surveys. We note that both reported barriers and length of time to complete daily surveys were higher in farmworkers with less than 8th grade education; even in this group, all completed surveys required 8 minutes or less. Across the entire sample available at follow-up, the average length of time to complete surveys was 5 minutes.

Study Retention and Mobile Phone Loss

As noted, most participants, (41/55) 75%, were maintained throughout the 30-day intervention trial. We examined those lost to the study (n=14). There were two participants that initially self-reported as being over the age of 18, and subsequently reported that they were 17 years old; several were not able to complete follow-up surveys (n=5) because of travel to Mexico to visit sick family or friends; and some had lost their work (n=7), as migrant labor is seasonal and often unstable. Among those who lost work, the individuals did not complete the intervention given that the primary goal of the intervention evaluation stage was to examine the impact on PPE use at work, and we collected data on those participants who worked throughout the 30 day study period. Overall, attrition did not appear to be due to “actual” concerns with the intervention or mHealth procedures, but rather seemed largely driven by external factors. Participants were asked to return the study mobile phones at the conclusion of the intervention pilot, and phone loss was low; (50/55) 90% of phones were returned at study completion. Even among the 14 participants not successfully completing the intervention component, 9 (64%) managed to return the phone to study staff.

Table 3. mHealth message satisfaction of ¡Protéjase! feasibility study at follow-up (n=41).

		n	%
What was the most useful type of information?			
	Health effects about pesticides	18/41	44
	Risks for my family	9/41	22
	Reminders about wearing PPE	7/41	17
	Tips on how to use PPE	6/41	15
	Don't know/not sure	1/41	2
What impacts did the messages have on PPE use?			
	A big increase in my use of PPE	17/41	41
	A small increase in my use of PPE	4/41	10
	No change in my use of PPE	9/41	22
	Decreased my use of PPE	4/41	10
	Don't know/not sure	7/41	17
What did you think of the messages you received?			
	I liked the messages, no need for changes	22/41	54
	I liked the messages, but they need refining	5/41	12
	Some messages were easier to understand than others	9/41	22
	All messages were difficult to read/understand	3/41	7
	Don't know/not sure	2/41	5
What barriers did you encounter while using the mobile phone?			
	None	30/41	73
	Difficulty in using/navigating the mobile phone to take survey	1/41	2
	Screen of the mobile phone froze	3/41	7
	Issues with battery (low battery)	6/41	15
	Fonts size made it difficult to read	1/41	2

Discussion

Principal Findings

¡Protéjase! was developed to increase PPE use in Mexican farmworkers through tailored prevention messages. Our evaluation showed that the program was viewed by workers as acceptable and appropriate to their cultural attitudes, and demonstrated very strong feasibility as an integrated intervention platform (PPE provision coupled with an individually and dynamically tailored mHealth motivational app). Satisfaction with the PPE component of the intervention was primarily linked to farmworkers' consideration that the PPE was comfortable and would not (or minimally) negatively impact work productivity. Also, the individualized messages were perceived as most helpful when they communicated health risks, or placed messages in the context of how to protect the family.

Previous literature strongly suggests that farmworkers often perceive PPE as disruptive to work efficiency and, when this is the case, farmworkers are not inclined to wear it. For example, Quandt et al [18] report that almost half of 197 farmworkers did not wear safety glasses because they prevent workers from distinguishing between the leaf colors of plants during harvest. A more recent intervention by Strong et al [19] reported that although pesticide safety knowledge scores increased in response to an intervention, change in glove and safety glasses use were unchanged because of impractical PPE. Moreover, the literature also strongly recommends that the impractical function of PPE is a primary barrier that must be overcome to boost pesticide safety behaviors among farmworkers [20].

¡Protéjase! begins to respond to the challenge about PPE impracticality by providing farmworkers with PPE that the workers perceived as comfortable to wear, but that did not meaningfully slow their production. Moreover, farmworkers felt that having comfortable PPE increased their use of it. This is notable, as it is well established that PPE has the potential to significantly lower pesticide exposure levels [2-6]. If farmworkers are able to increase their PPE use through the provision of high quality PPE (and the receipt of appropriate risk messaging through a mHealth app or the receipt of appropriate risk messaging through a mHealth app, discussed below), it is likely that their exposures may also be reduced.

Additionally, farmworkers responded well to the messaging components of the study, and the majority of participants found the mHealth platform on provided mobile phones a viable option

for their daily use. This may be due, at least in large part, to the substantial preexisting ownership of (and, presumably, familiarity and comfort with) mobile phones. This, coupled with previous research demonstrating that farmworkers have broad access to mobile phones [9], suggests that mHealth may hold tremendous potential as a platform for interventions for farmworkers. We did not, however, attempt to use participants' own mobile phones in our study to avoid an array of logistical issues (eg, software and other procedural features need to work correctly across different phone operating systems and versions, various screen sizes, compatibility among various platforms, etc); rather, for this initial study, we provided all participants with phones for use during the study period. As such, future work should evaluate the use of personal phones in order to more readily be able to bring interventions to scale.

Finally, we established that farmworkers were willing and able to fully participate in mHealth programs to increase PPE use. Others have previously suggested that as technology becomes increasingly familiar to farmworkers, that mHealth approaches/services have tremendous potential to provide access to a wide range of their health care needs [9-11]. In the future, mHealth interventions like ¡Protéjase! may provide a framework that can be replicated and feasibly applied to a broad array of public health issues, ranging from health promotion to interventional behavior modification for chronic illness. In this regard, utilizing a mHealth approach to collect data from farmworkers as they go about their daily lives may be an important new area that strengthens existing work in that population by enhancing the accuracy and ecological validity of behavioral reports in safety and health research.

Limitations

Although participants largely viewed our intervention as successful, there are areas for improvement. For example, our intervention language was created at a 5th grade level of education. Despite this, workers recommended tailoring language and making the intervention more accessible for low-literacy workers. National estimates suggest that farmworkers generally have low-levels of education [8] and most farmworkers in our study had less than a high school education. Although only (3/41) 7% of participants had issues with reading the messages, future versions of our program may be able to resolve literacy issues by using voice automation to improve its acceptability in low-literacy workers. Automated programs have proved largely successful in other mHealth studies for low-literacy farmworkers [10,11] and might improve the feasibility and implementation of our program. We also note that messages in future versions of our program might be extended to encompass additional safety domains. For example, to remind workers when they should wash and launder their PPE, as PPE is most effective when it is clean. Finally, we note that this study takes place in Texas only, and has a small sample size. Our findings may not be generalizable to all farmworkers.

Conclusions

In summary, the use of an integrated intervention approach, coupling the provision of optimized PPE with a supportive mHealth app, to deliver ¡Protéjase! to farmworkers was well-received, and we see this approach as an innovative way to engage farmworkers for pesticide protection. Additionally, mHealth approaches like ¡Protéjase! might serve as model programs that could be altered to address other health issues in farmworker populations by dynamically tailoring messages to their specific daily needs. In this regard, the mHealth platform can be a useful design for integrating culturally appropriate health messaging and data collection for pesticide safety and health information delivery.

Conflicts of Interest

None declared.

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Abbreviations

app: application
PPE: personal protective equipment
¡Protéjase!: Protect Yourself!
TMC: Teaching and Mentoring Communities, Inc

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Original Paper

Community Engagement to Optimize the Use of Web-Based and Wearable Technology in a Cardiovascular Health and Needs Assessment Study: A Mixed Methods Approach

Leah R Yingling[1], BS; Alyssa T Brooks[2], PhD; Gwenyth R Wallen[2], RN, PhD; Marlene Peters-Lawrence[3], RN; Michael McClurkin[1], BA; Rebecca Cooper-McCann[2], BS; Kenneth L Wiley Jr[4], PhD; Valerie Mitchell[1], BA; Johnetta N Saygbe[1], BS; Twanda D Johnson[2], ABA; Rev. Kendrick E Curry[5], PhD; Allan A Johnson[6], PhD; Avis P Graham[6], PhD, RD, LDN; Lennox A Graham[6], DM; Tiffany M Powell-Wiley[1], MD, MPH

[1]Cardiovascular and Pulmonary Branch, Division of Intramural Research, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD, United States

[2]Clinical Center, National Institutes of Health, Bethesda, MD, United States

[3]Office of the Clinical Director, Division of Intramural Research, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD, United States

[4]Division of Genomic Medicine, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD, United States

[5]Pennsylvania Avenue Baptist Church, Washington, DC, United States

[6]College of Nursing and Allied Health Sciences, Howard University, Washington, DC, United States

Corresponding Author:
Tiffany M Powell-Wiley, MD, MPH
Cardiovascular and Pulmonary Branch
Division of Intramural Research, National Heart, Lung, and Blood Institute
National Institutes of Health
Bldg 10, 5-3330
10 Center Drive
Bethesda, MD, 20892
United States
Phone: 1 301 594 3735
Fax: 1 301 402 0888
Email: tiffany.powell@nih.gov

Abstract

Background: Resource-limited communities in Washington, D.C. have high rates of obesity-related cardiovascular disease in addition to inadequate physical activity (PA) facilities and limited Internet access. Engaging community members in the design and implementation of studies to address these health disparities is essential to the success of community-based PA interventions.

Objective: The objective of the study was to use qualitative and quantitative methods to evaluate the feasibility and acceptability of PA-monitoring wristbands and Web-based technology by predominantly African American, church-based populations in resource-limited Washington, D.C. neighborhoods.

Methods: To address cardiovascular health in at-risk populations in Washington, D.C., we joined community leaders to establish a community advisory board, the D.C. Cardiovascular Health and Obesity Collaborative (D.C. CHOC). As their first initiative, the Washington, D.C. Cardiovascular Health and Needs Assessment intends to evaluate cardiovascular health, social determinants of health, and PA-monitoring technologies. At the recommendation of D.C. CHOC members, we conducted a focus group and piloted the proposed PA-monitoring system with community members representing churches that would be targeted by the Cardiovascular Health and Needs Assessment. Participants (n=8) agreed to wear a PA-monitoring wristband for two weeks and to log cardiovascular health factors on a secure Internet account. Wristbands collected accelerometer-based data that participants uploaded to a wireless hub at their church. Participants agreed to return after two weeks to participate in a moderated focus group to share experiences using this technology. Feasibility was measured by Internet account usage, wristband utilization, and objective PA data. Acceptability was evaluated through thematic analysis of verbatim focus group transcripts.

Results: Study participants (5 males, 3 females) were African American and age 28-70 years. Participant wristbands recorded data on 10.1±1.6 days. Two participants logged cardiovascular health factors on the website. Focus group transcripts revealed that participants felt positively about incorporating the device into their church-based populations, given improvements were made to device training, hub accessibility, and device feedback.

Conclusions: PA-monitoring wristbands for objectively measuring PA appear to be a feasible and acceptable technology in Washington, D.C., resource-limited communities. User preferences include immediate device feedback, hands-on device training, explicit instructions, improved central hub accessibility, and designation of a church member as a trained point-of-contact. When implementing technology-based interventions in resource-limited communities, engaging the targeted community may aid in early identification of issues, suggestions, and preferences.

ClinicalTrial: Trial Registration: ClinicalTrials.gov NCT01927783; https://clinicaltrials.gov/ct2/show/NCT01927783 (Archived by WebCite at http://www.webcitation.org/6f8wL117u)

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KEYWORDS

mHealth; physical activity; community-based participatory research; obesity; African Americans; activity monitoring; qualitative research; focus groups; community

Introduction

Cardiovascular Disease in the United States

Cardiovascular disease (CVD) is the leading cause of death in the United States [1]. It is recognized that modifiable lifestyle risk factors, including insufficient physical activity (PA), are associated with increased risk of adverse health outcomes from CVD [2,3]. Despite the considerable health benefits associated with regular participation in PA, less than 25% of US adults meet the prescribed PA guidelines of at least 30 minutes of moderate-intensity aerobic activity five days per week, 20 minutes of vigorous-intensity aerobic activity three days per week, or an equivalent combination of the two, plus muscle-strengthening activities on at least two days per week [4]. Of particular concern are individuals in economically disadvantaged and resource-limited communities, who are more likely to report being physically inactive and suffer disproportionately from obesity and obesity-related cardiovascular risk factors [5-7].

Physical Activity Interventions

Recognizing the potential for broad impact and sustainability, recent work has promoted population-based strategies for improving PA levels [8]. Community-based programs may be an effective population-based strategy for delivering PA interventions in underserved, economically disadvantaged communities, as they have demonstrably leveraged the local built environment and empowered community members [9]. Methods for implementing a PA intervention in a community-based setting vary across studies. In a review of existing community-based interventions promoting PA and healthy eating, all studies targeting adult populations implemented a PA component [10]. Of those PA interventions set in specifically resource-limited communities, most relied on self-report and did not include objective PA measures (eg, accelerometers, pedometers) [10]. Of the reviewed interventions set in specifically resource-limited communities, none used emerging health technologies that provide feedback, such as wrist-worn electronic activity monitors to objectively measure PA.

Wearable, electronic activity monitors have been identified recently as a potential tool to integrate into population-based PA interventions [11,12]. Electronic activity monitor systems have been defined previously as a wearable device that objectively measures lifestyle PA and can provide feedback, beyond the display of basic activity count information, via the monitor display or through a partnering application to elicit continual self-monitoring of activity behavior [13]. They offer the potential to extend PA interventions beyond the clinical setting to those with limited access to care; however, the feasibility of incorporating electronic activity monitors and Web-based technology as part of a PA intervention in community-based settings is unknown. Thus, evidence-based PA interventions that use technology in resource-limited, community-based programs warrant investigation. Understanding how electronic PA monitors can be optimized in community-based interventions may reveal opportunities to increase PA, to reduce cardiovascular (CV) health disparities, and to improve clinical outcomes among economically disadvantaged populations.

Community leaders in our target population proposed the engagement of church members to pilot test the feasibility and acceptability of using technology to evaluate health behaviors in the resource-limited Washington, D.C., communities. Therefore, we conducted a mixed methods pilot study to: (1) evaluate the use of an electronic PA-monitoring wristband for objectively measuring PA and the use of Web-based technology for monitoring CV health factors; (2) illuminate advantages and disadvantages of implementing technology-based PA interventions in a resource-limited setting; and (3) explore how community-based participatory research (CBPR) can shape PA interventions in resource-limited, community-based programs.

Methods

Study Approval

The NHLBI Institutional Review Board (National Institutes of Health, NIH, Protocol 13-H-0183) approved the CV Health and Needs Assessment and the CV Health and Needs Assessment

Qualitative Study. All participants provided written informed consent.

Study Design

We conducted a CBPR mixed methods study that incorporated a moderated focus group and pilot testing of a two-part PA-monitoring system: a PA-monitoring wristband (Dynamo Activity Tracker, Oregon Scientific, Tualatin, OR) with a centralized hub for data download in a community location, and a secure Internet account for manual tracking of CV health factors (Vignet Corp, McLean, VA). Figure 1 shows the data collection process. The particular PA-monitoring system featuring a Health Insurance Portability and Accountability Act-compliant centralized hub was selected to address secure data transfer issues and potential technology access barriers. The selected system made secure uploading and viewing data possible for all participants regardless of computer, mobile device, or Internet access.

To consult on the planning and implementation of a community-based initiative, we established the D.C. CV Health and Obesity Collaborative (D.C. CHOC), a community advisory board (CAB) comprised of a diverse group of community leaders, church leaders, and coinvestigators. It was at the recommendation of members of the D.C. CHOC that we conducted a focus group and pilot testing with a sample from the target church-based population for feedback on the proposed PA monitor, prior to testing on a larger population in the CV Health and Needs Assessment. The pilot testing that is the focus of this study was called the CV Health and Needs Assessment Qualitative Study.

The focus group was conducted after two weeks of PA monitoring, a testing period commensurate with similar mobile and mobile phone-based activity tracking studies [14,15]. The moderator(s) sought insight into participants' experiences using the wrist-worn PA monitor, the hub for PA monitor data upload, and the Web-based account for monitoring PA and other CV health factors. The outcomes of interest in our study were: (1) feasibility of the PA monitoring system as measured by Internet account input, wristband utilization frequency, and objective PA data and (2) acceptability of the system as measured by results of a moderated focus group discussion designed to elicit participants' opinions about their experiences with the device and to prompt their suggestions for incorporating similar technologies in future behavioral weight loss interventions within their communities.

Figure 1. Secure data collection process; Cardiovascular Health and Needs Assessment Qualitative Study, 2014. HIPAA: Heath Insurance Portability and Accountability Act.

Study Population

Participants were recruited from December 2013 to January 2014 from three churches in Wards 5, 7, and 8 of Washington, D.C. These are three Washington, D.C. wards with a median household income significantly lower than all of Washington, D.C. and where resources for PA and healthy nutritional options are most limited [16]. Participants were congregants at one of the participating churches, age 19-85 years, provided informed consent, and possessed sufficient English language proficiency to carry out study tasks. No more than 15 participants were recruited for the study, and 7-9 participants were anticipated, a total that is within the recommended range for qualitative research group discussion and is comparable to other mobile health (mHealth) and electronic health (eHealth) initial pilot testing groups [14-18].

Physical Activity Monitoring System

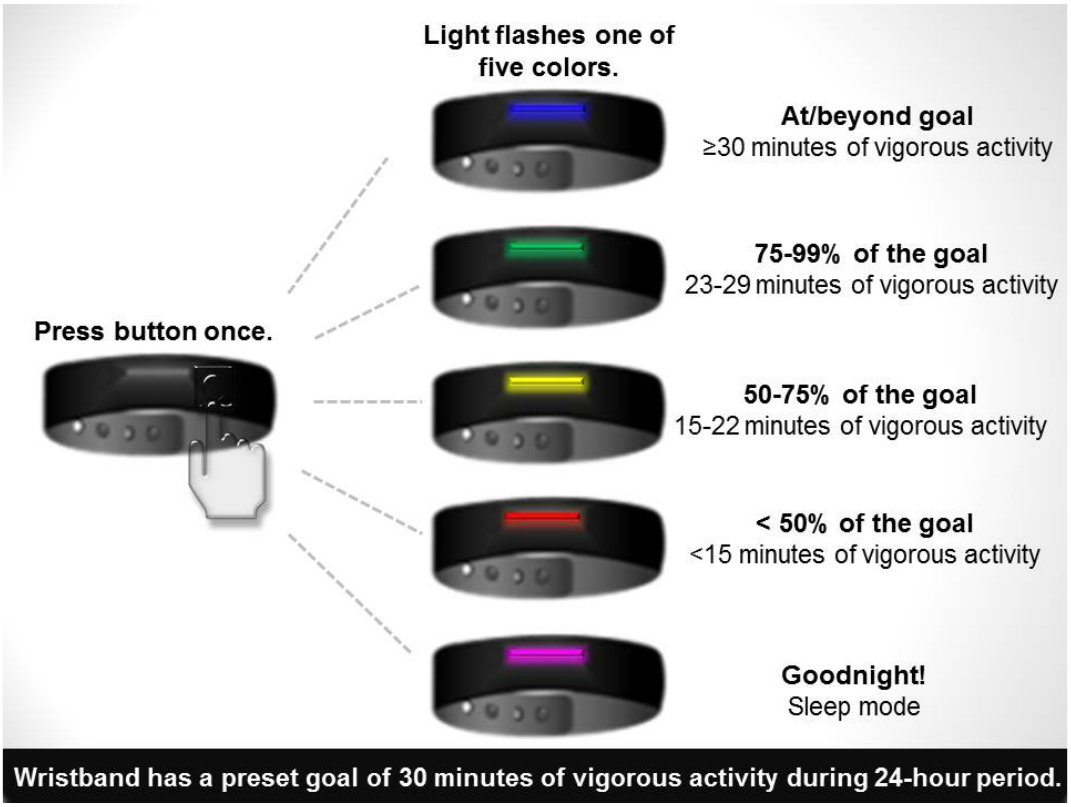
Physical Activity Monitoring Wristband

Each participant was provided a wrist-worn wireless activity and sleep wristband to collect and self-monitor PA and sleep duration for two weeks. A thirty-minute wristband training session was provided on the day of device distribution, and a written instruction manual (Figure 2 shows this) was distributed to all participants.

The wrist-worn PA monitor collected accelerometer-based data on the amount and intensity of PA (eg, steps taken, calories burned, distance travelled, and minutes of vigorous activity). The wristband used a colored-light system (Figure 3 shows this) to communicate PA progress to the participant. Though participants were instructed not to modify their routine PA, the wristband featured a preset goal of 30 minutes of vigorous activity throughout a 24-hour period. Pressing the wristband button prompted the wristband light to display a specific color. The various colors indicated sleep mode, battery depletion, or progress toward PA goals.

Figure 2. Instruction manual (page 1) for syncing physical activity-monitoring wristband with hub; Cardiovascular Health and Needs Assessment Qualitative Study, 2014.

Figure 3. Physical activity-monitoring wristband colored light system; Cardiovascular Health and Needs Assessment Qualitative Study, 2014.



Physical Activity Monitoring Data Collection

All participants uploaded recorded PA and sleep data wirelessly from their wristband devices to the centralized hub on the final day of the study. The hub captured and transmitted the previous fourteen days of PA data. After a successful upload, the hub displayed the past 24-hours of PA data to the participant. Participants were able to synchronize their wristbands with the hub at any point during the study period. After successfully synchronizing their wristbands with the hub, participants had access to their recorded PA accelerometer-based data in addition to all self-logged data on a website. Figure 4 shows the wristband synchronizing process. A hub was provided to each church.

Figure 4. Physical activity-monitoring wristband with hub; Cardiovascular Health and Needs Assessment Qualitative Study, 2014.

Internet Account for Tracking Physical Activity Data

Each participant was provided with a secure account (using a deidentified username and password) on a website associated with the PA-monitoring wristband. Participants were trained on general website use and how to log self-reported PA, weight, dietary intake, heart rate, blood pressure, and blood glucose levels, if measured. Self-reporting of these measures was optional, and participants could do so from a personal or church-based computer. Investigators monitored usage of the wristband and website by collecting deidentified data from a website during the two-week study.

Focus Group

At the end of the two-week period, participants participated in a moderated focus group to provide feedback on their experiences using the PA-monitoring wristband, the hub, and the Internet account. Participants were remunerated with a US $25 gift card, compatible with time required for the focus group.

One moderator, who acted as a facilitator, led the focus group. There were two comoderators that assisted with the focus group. The moderator led the discussion using a Moderator's Guide (see Multimedia Appendix 1), which included preselected questions and probes. The questions were grouped in categories recommended by Krueger [19]: opening, introductory, transition, key, and closing. The comoderators recorded notes, made observations, and managed the equipment (tape recorder, microphones, etc).

Quantitative Data Analysis

Quantitative accelerometer-based data were collected from all participants' wristbands on the final day of the study. All quantitative analyses were performed in SAS version 9.3 (SAS Institute Inc, Cary, NC, USA).

Wristband and Website Utilization Frequency

Wristband utilization frequency was measured by the number of days with wristband-measured activity. The number of self-logged entries per participant measured Internet account usage.

Objective Measurements

Quantitative data included steps taken (measured in strides), distance travelled (measured in miles), vigorous activity (measured in minutes), calories burned (measured in kilocalories), and sleep time (measured in hours). The final day of collected data was omitted from the analysis, as it represented only a partial day and likely was not representative of a typical full day's PA measurements. Days with no recorded PA data were considered "missing" and were not included when calculating average PA measures per day.

Qualitative Data Analysis

The focus group was audio-recorded, and the recording was transcribed verbatim by an independent clinical research organization (Social Solutions International, Inc, Silver Spring, MD, USA). A member of the research team, who listened to the audio files to verify they were transcribed verbatim, performed an internal reliability check on the transcript. As a preliminary step in the qualitative thematic analysis, four members of the research team developed a codebook, or dictionary of themes, based on participant responses. Four coders, who independently reviewed the interview transcripts, assessed evidence of each code or theme. Each coded theme was accompanied by an operational definition that allowed for clarity and consistency in the coding process. After data were transcribed and cross-checked by the four coders, NVivo (version 9.0) was utilized for further qualitative analysis. Discordant coding was discussed until consensus among the four coders was achieved. Once the iterative process of consensus building was complete, an NIH intramural qualitative research expert validated the themes and coding.

To ensure that the trustworthiness of the qualitative data was preserved, three criteria were used to assess rigor: "creditability", "auditability", and "fittingness" [20], as shown in Multimedia Appendix 2 (see Multimedia Appendix 2). An intramural mixed methods expert, to ensure creditability, validated the themes (ie, truth of the findings) [20]. To maintain auditability (ie, "the adequacy of the information leading the reader from the research question and raw data through various steps of analysis to the interpretation of findings") [20] and fittingness (ie, "faithfulness to everyday reality of participants") [20] of the qualitative data, a thorough description of the interview setting was reported and selected quotes that are illustrative of each designated theme are displayed in the tables to highlight pertinent findings.

Results

Demographic Characteristics

There were eight individuals that participated in the two-week pilot testing period and the subsequent focus group. Among the participants, 63% (5/8) were male, the mean age was 53.3 ±12.2 years, all participants were African American, and all attained higher than a high school education. Demographic characteristics for the study population are presented in Table 1.

Table 1. Participant baseline characteristics in the CV Health and Needs Assessment Qualitative Study, 2014 (n=8).

Variable		
Sex, n (%)		
	Female	3/8 (37)
	Male	5/8 (62)
Age, years		
	Mean (SD)	53.3 (12.2)
	Range, years	28-70
Race, n (%)		
	Black/African American	8/8 (100)
Marital status, n (%)		
	Single	1/8 (12)
	Married	7/8 (87)
Education, n (%)		
	Some college	3/8 (37)
	College degree	2/8 (25)
	Technical degree	1/8 (12)
	Graduate/professional degree	2/8 (25)
Annual household income US (n=7), n (%)		
	< $60,000	2/7 (28)
	≥ $60,000	5/7 (71)

Quantitative Data

Wristband and Website Utilization Frequency

Of the 13 possible full days of PA-monitoring wristband readings, participant wristbands provided readings for 10.1 ± 1.6 days. Most participants (63%, n=5/8) registered 10 days or more of PA data. There were five participants (63%, n=5/8) that utilized the wristband's sleep function more than once. Due to a system issue, depleted battery, or lack of participant compliance, only 12% (n=1/8) of participants had a complete 13-day dataset. There were two participants (25%, n=2/8) that used the website to track additional CV-related health factors by logging body weight, blood glucose level, PA minutes, and hours of sleep, or hours of sleep.

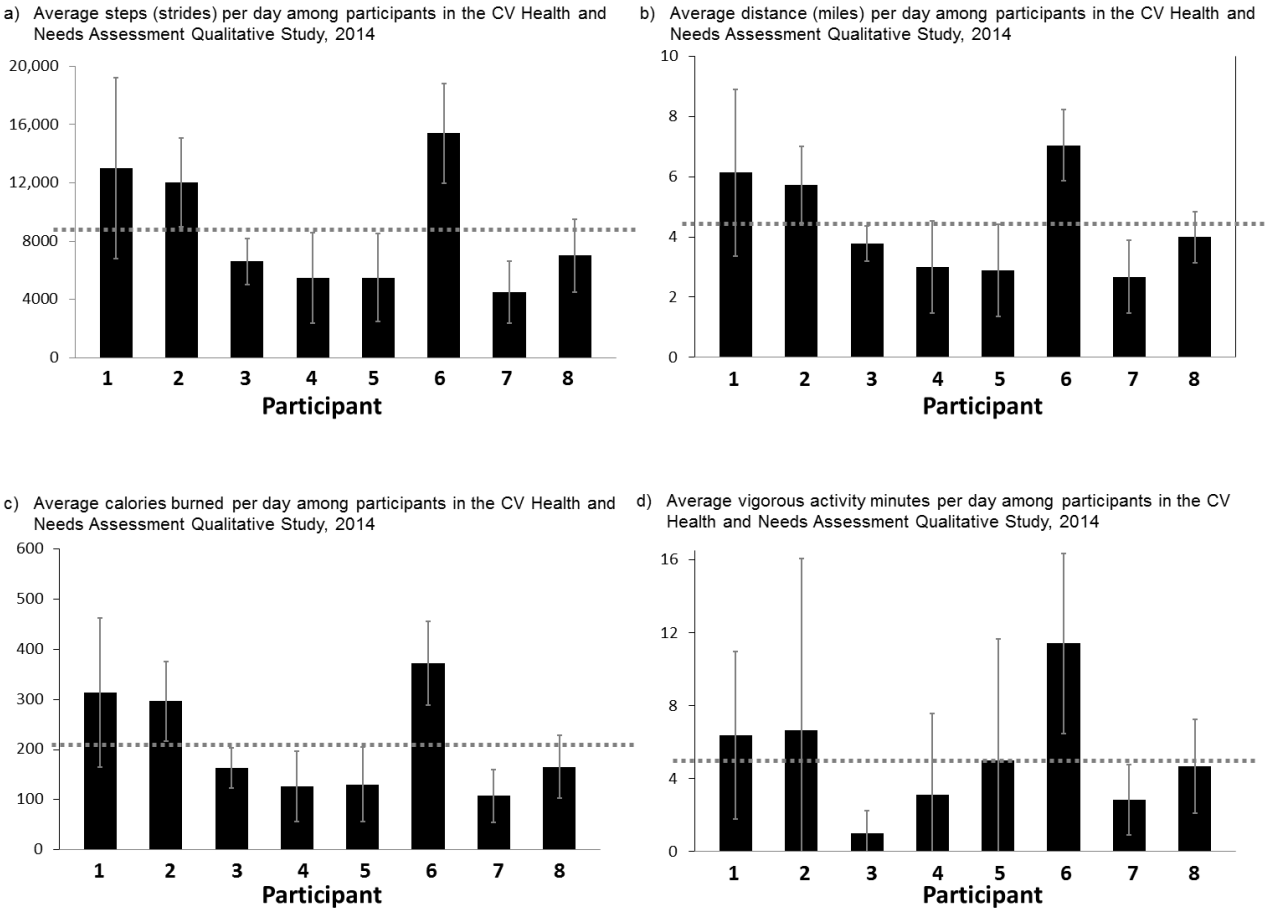
Objective Measurements

Figure 5 shows average daily steps, distance, calories burned, and vigorous minutes for each participant. For the days on which steps were registered, mean steps per day among participants was 8693 ± 3124 steps. Among participants, the maximum steps per day were 15,417 ± 3420 steps and the minimum was 4155 ± 2323 steps. For the days on which data were measured, mean distance travelled per day among participants was 4.40 ± 1.36 miles, mean calories burned per day was 210 ± 76.6 calories, and mean vigorous activity minutes per day among participants was 5.13 ± 4.47 minutes. There were six participants (75%, n=6/8) that registered at least one day with no vigorous activity minutes.

Qualitative Data

There were eight themes that emerged from the focus group and are shown in Textbox 1. Selected quotes from participants associated with each theme and subtheme are presented in Table 2.

Figure 5. Quantitative participant (n=8) wristband data — Cardiovascular Health and Needs Assessment Qualitative Study, 2014. M=Mean; a) Overall average steps, M(SD) = 8693 (3124) strides per day; b) Overall average distance, M(SD) = 4.40(1.36) miles per day; c) Overall average calories burned, M(SD) = 210(76.6) calories per day; and d) Overall average vigorous activity minutes, M(SD) = 5.13(4.47) minutes per day.



Textbox 1. Focus group themes and subthemes - CV Health and Needs Assessment Qualitative Study, 2014.

- Feedback
  - Desire for immediate device feedback
  - Accessibility of feedback about PA
- Design of PA Monitor
  - Physical discomfort
  - Features
- Ambiguity over project goals
- Issues about hub
- Website for supporting PA monitors
- Feasibility of using PA-monitoring system
- Suggestions for improvement

Table 2. Focus group themes, subthemes, and quotes - CV Health and Needs Assessment Qualitative Study, 2014.

Theme and subthemes		Illustrative quotes
Feedback		
	Desire for immediate device feedback	That's the fundamental problem...there's no immediate feedback...We need some kind of feedback besides these lights. [Male, age 49]
		I was thinking about what [participant name] said about the vibration...Maybe something to vibrate when I'm at 50, 60 or 100% [of daily recommended physical activity]. [Male, age 55]
	Accessibility of feedback about PA	And I'm not always near a hub so the only feedback I had were those lights. [Male, age 49]
		The definition of what's vigorous...What does that really mean? I work out 45 minutes every day. I lift, do treadmill and do crunches but my arm's not moving enough for you. [Male, age 55]
Design of PA monitor		
	Physical discomfort	I had no way to clip this device like I clip on my watch...During the day I always had to touch it to make sure it didn't come off. Maybe a different kind of clamp with like a watch clamp. [Male, age 55]
		I had major skin irritations from it. From the metal part that touched my arm. I still have irritation now. [Female, age 59]
	Features	Even though it says purple sometimes it looked more like red to me, so I don't know...The colors should be more distinct. [Male, age 49]
		The device was kind of bulky around my wrists. I was trying to put my shirt on, move the device up and down my wrist to make sure I could get my shirt over it or keep my shirt over top of it. [Male, age 55]
Ambiguity over project goals		What I understood...is that you measure what you do normally; don't do anything extra or less. [Female, age 62]
		The goal of this was to show the green. That's why I thought we were working so hard to get it done. [Male, age 55]
Recording PA		We just took the band off to sleep because...the light was a problem the first night...When I went on the computer, I put how many hours I slept. [Female, age 62]
		A lot of my activity's in the water, and since we couldn't do that you have to put them in the computer. [Female, age 62]
Issues about hub		[Our hub] didn't work at our church at all. [Female, age 69]
		We had to go outside to one of our other buildings to try and sync it...The timing trying to get it just right between the two services [was challenging]. [Male, age 59]
Website for supporting PA monitors		I couldn't pull it up on my phone, which is where I am most of the time. [Female, age 43]
		I would have preferred to have an app. [Male, age 49]
Feasibility of using PA-monitoring system		I think a centrally located area in church that's not lock-and-key will make the user...more like, "Okay, I can sit there and download it", not have to run around, "Who has the key?", they stand there while you're doing it, then they lock up the room when you leave. [Male, age 55]
		I was as at church but not able to get to the actual [hub], because where I was located at that point in time. Because...you know I have a lot going on. So it's like I can get it this point in time or just can't. [Female, age 62]
Suggestions for improvement		You may want...a point person in the church that has been trained in the docking system, so they don't have to call you all the time, train somebody in the church so they can troubleshoot for you real quick. [Male, age 55]
		Maybe social media...so we can share our results. [Male, age 49]

Focus Group Themes

Regarding the feedback theme, multiple participants reported a desire for immediate, more accessible feedback complementary to the colored lights on the wristband. Additionally, participants tended to be disappointed with their personal vigorous activity minutes and requested more information on the types of activity that would register as vigorous.

Regarding the PA monitor design; participants raised concerns about physical discomfort and the monitor features. Some participants recommended a different clasp to prevent accidental detachment, and two participants experienced skin irritation where the wristband was secured. Several participants experienced difficulty differentiating between the colored lights, and a few participants found the wristband to be bulky in size.

An overarching theme was the ambiguity of the project goals outlined in the initial training. During training, participants were

instructed not to modify their routine PA; however, the preset 30-minute vigorous activity goal of the wristband led some participants to modify their activities in pursuit of "show[ing] green" by reaching 30 minutes of vigorous activity in a single 24-hour period. In relation to the theme of recording PA, those participants who engaged in activities not measured by the wristband (eg, water sports, weight lifting, etc) preferred if the wristband would have captured all PA, regardless of its nature.

Participants also discussed issues about the centralized hub and its availability for synchronizing. There was one participant that reported that the hub did not work at his church, which restricted synchronizing during the two-week period. At another church, the hub was reported to be inconvenient to access.

Regarding the website for supporting the PA monitor, most participants reported no use of the site and preferred alternative options for manual entries and self-monitoring, including a mobile phone application (app) for tracking CV health factors and PA. With regards to implementation of the PA-monitoring system, participants suggested identifying a trained point-person for each church, and sharing PA data through social media to add a competitive element and an aspect of support. Additionally, participants reported that the feasibility of the PA-monitoring system would be contingent on the implementation of specific changes, such as moving the hub to a central area, extending hub hours, and identifying a point-person within the church for expedited troubleshooting.

Changes Made

The changes made for future testing of the PA technology in Washington, D.C., community-based populations based on the qualitative focus group data are documented in Table 3. We addressed several concerns by modifying how the PA wristband monitor training was conducted in the larger Washington, D.C., CV Health and Needs Assessment. We also revised the information provided during the PA wristband monitor training and in the wristband instruction manual. Addressing the ambiguity of "vigorous activity", we provided a clearer and more relatable definition of vigorous activity to participants (ie, activities that require hard physical effort and cause large increases in breathing or heart rate such as running; aerobics; using the elliptical machine, with arms; or playing a sport like football, basketball, soccer, or tennis). To address design concerns of the PA monitor, we ensured proper wristband attachment during training and warned participants of potential skin irritation issues. Participants were advised to wear the wristband loosely. To address potential misunderstandings of the colored-light system, we incorporated a detailed description of the wristband's colored lights during device training and on the "Helpful Hints" sheet, a frequently asked questions sheet created for at-home reference.

Table 3. Lessons learned and changes made for testing PA technology in broader community-based populations.

Theme and subthemes		Changes made
Feedback		
	Desire for immediate device feedback	• Taught participants how to use the wristband's colored lights to monitor activity minutes (ie, lights progress through series of colors as participant approaches 30 minutes of vigorous activity) • *Red*=less than 50% of goal • *Yellow*= 50-75% of goal • *Green*=75-99% of goal • *Blue*=100% or above goal
	Accessibility of feedback about PA	• Provided clear definition of vigorous activity in both the training and instruction manual (ie, activities that require hard physical effort and cause large increases in breathing or heart rate, eg, running, aerobics, using the elliptical machine, with arms, or playing a sport like football, basketball, soccer, or tennis)
Design of PA monitor		
	Physical discomfort	• Informed participants about wristband-related skin irritation during device training and in the instruction manual • Instructed participants to wear the wristband loosely if irritation is likely • Ensured that participants latched wristband properly during device training
	Features	• Incorporated detailed section on the wristband's colored lights during device training and on the "Helpful Hints" for at-home reference
Ambiguity over project goals		• Redesigned education component to explicitly state project goals (ie, participants should continue with routine PA and not change behavior) • Explicitly stated project goals in written instruction materials • Developed two instructional training videos on device and hub usage that were used during device training and made publically available after the event for participant reference • Incorporated more hands-on in-person training where participants could use the website, test wristband lights, and upload wristband data
Recording PA		• Instructed participants to test sleep mode during device training • Educated participants on the use of sleep mode, but purposefully did not emphasize its use • Tested website to manually input sleep and PA during device training • Developed instructional video on recording PA that was used during hub and device training and was made publically available during the study for participant reference
Issues about hub		• Corresponded weekly with device company and participants to identify and troubleshoot hub issues • Incorporated troubleshooting report sheet next to hub for streamlined reporting • Provided participants with a schedule of "hub hours" and the option to synchronize wristbands at any of the participating churches • Identified a point-person within church community to aid in troubleshooting minor hub issues
Website for supporting PA monitors		• Incorporated website Q&A and an opportunity to log-in during device training • Corresponded regularly with participants to troubleshoot website challenges
Feasibility of using PA-monitoring system		• Chose hub locations within churches that were accessible for all participants
Suggestions for improvement		• Identified point-person within church community to aid in troubleshooting and correspondence between participants and research team during study period

With ambiguity over project goals as an overall participant concern, we redesigned the written and in-person education component. In training, we explicitly stated project goals verbally and in writing. Additionally, we developed two instructional training videos on device and hub usage that were used during device training and then made publically available after the event for participant reference. We also incorporated more hands-on, in-person training where participants could trial the website, test wristband lights, and upload wristband data.

Due to participant concerns about the hub, we improved our troubleshooting correspondence. We communicated weekly

with the device company and the participants to identify and address hub issues, and we incorporated a report sheet next to the hub for streamlined reporting of issues. To address hub availability issues, we provided participants with a schedule of "hub hours" and the option to synchronize their wristbands at any of the participating churches. As per participant recommendation, we identified a point-person within each church community to aid in all troubleshooting and to lead correspondence between participants and the research team during the study period.

Discussion

Principal Findings

The objective of this mixed methods pilot study was to engage community members in the evaluation of the feasibility and acceptability of a wrist-worn PA monitor and a CV-health factor tracking website for measuring PA and tracking CV-related health factors prior to implementation in larger groups in similar resource-limited, community-based settings. Both quantitative and qualitative findings revealed that wrist-worn PA monitors can successfully capture and communicate objective PA data (eg, steps, miles, calories, and vigorous activity minutes) on the majority of days and that, contrary to our anticipation, Internet account usage for inputting CV-health related factors was minimal. Strengths and weaknesses of the PA-monitoring system and the user experience were identified and categorized into themes, which improved the PA wristband monitor implementation in our large-scaled study.

This is one of the first studies, to our knowledge, to demonstrate wrist-worn PA monitor systems as a feasible and acceptable means for objectively measuring PA in resource-limited, community-based settings. Our findings suggest that using wrist-worn PA monitors to track PA in resource-limited, community-based populations appears both acceptable and dually beneficial, by providing a feasible way to capture objective PA data and to communicate feedback on PA levels to participants. Additionally, we found that community engagement is critical when integrating new technologies in community-based, resource-limited settings, as it both enhances understanding of the community and the technology environment and aids in identifying strengths and weaknesses of the proposed intervention.

Wrist-Worn Physical Activity Monitors as Potential Physical Activity Intervention Tool in Community-Based Settings

In a review of PA interventions targeting African American adults, Whitt-Glover et al [21] called for the use of community-based interventions, as "utilizing resources within the community may increase sustainability compared with laboratory-based interventions". There is evidence suggesting that, despite the practical challenges, technology-driven interventions may succeed in community-based settings [22]. To date, technology-driven PA interventions have incorporated technology largely in two ways: to capture objective measurements (ie, pedometers, accelerometers) [21] or to aid in the delivery of the PA intervention (eg, Internet or text-based interventions, podcasts, mobile apps) [23-26]. Emerging mHealth technologies, specifically wearables, are becoming increasingly available and integrated into interventions that require activity tracking. Few prior studies have tested wrist-worn activity-tracking monitors in a community-based setting [21]. Our findings in a community-based setting, particularly participants' frequency of PA monitor use and recorded steps, compare favorably to recent studies in noncommunity-based settings testing wearable devices, which have demonstrated that PA interventions incorporating wrist-worn PA monitors are feasible and acceptable within specific populations and can successfully promote and track PA [11,27,28].

Wrist-worn PA monitors track similar quantitative PA data (eg, steps, miles) as the tools used in previous community-based PA studies (eg, pedometers, accelerometers), however, they often have the added benefit of providing comprehensible feedback to the user, a preference highlighted by participants in this study. Feedback from the mHealth wristband was limited in this study; however, the existence of commercial monitors that provide continuous real-time feedback increases the options available to interventionists and could minimize barriers to direct, real-time feedback. The feedback component provides an element of self-monitoring, often described as the "cornerstone" of behavioral interventions [29,30]. Early weight management studies found that more consistent self-monitoring improved weight control and increased the likelihood of participant engagement in the full intervention period [31]. In our study, participants responded positively to a feedback feature, as they also found it aided in self-monitoring, a finding similar among other wrist-worn PA monitor studies [11,27,28]. However, participants preferred a wristband with a more comprehensive and accessible feedback system, particularly one with a more distinct indication of when one enters the "vigorous activity" zone and when one achieves a certain percentage of the daily PA goal. Additionally, participants desired improved accessibility to raw PA data. In our study, participants could access their PA data on their Internet accounts after uploading PA data from their wristband to the central hub at their churches. Participants noted that improved access to feedback would likely increase their self-awareness and self-monitoring, a finding consistent with lifestyle behavior change literature [32-34].

When integrating technology in community-based interventions in resource-limited settings, differential technology access and usage must be acknowledged to reduce potential disparities. This is particularly of concern when developing technology-based interventions that target groups associated with decreased access to the Internet, specifically those of lower socioeconomic status, minority racial group or ethnicity, older age, and poorer health [35-40]. Disparities in wireless broadband adoption are well documented across Washington, D.C. wards. According to a website, wireless broadband adoption in Wards 5, 7, and 8 (66%, 55%, and 58%, respectively) is significantly lower than the remaining D.C. wards, where wireless broadband adoption is greater than 79% [41]. Previous work has demonstrated that utilization of eHealth technologies, predominantly those that relate to health seeking and health tracking, is largely influenced by Internet access and experience

in usage [42]. Incorporating a centralized hub did limit participants' ability to access quantitative PA data in real time; however, it had the added benefit of community-wide accessibility. The hub made uploading and viewing PA data possible for all participants regardless of computer, mobile device, or Internet access. Addressing these well-documented access barriers by incorporating a centralized hub ensures that the PA technology is equally accessible to all participants.

Kumanyika et al [43] highlighted the potential of eHealth and mHealth interventions for addressing obesity in minority youths and adults, calling first for the critical need for evidence to inform the development of eHealth interventions. Findings from this study suggest that an obesity intervention integrating mHealth technology for PA monitoring may be feasible in community-based, resource-limited communities. Advantages of incorporating mHealth technology for PA monitoring in an intervention include real-time data collection and the potential to deliver personalized feedback within the participant's natural environment. More evidence is needed to determine if incorporating PA-monitoring technology as part of a community-based intervention can improve clinical outcomes in resource-limited settings; however, it does appear to be a feasible and acceptable method to include in future PA studies of similar populations.

Community-Based Participatory Research as a Useful Approach for Implementing Related Physical Activity Technology in Community-Based Settings

Previous studies have demonstrated that when CBPR principles occur in collaboration with community partners, they serve as sustainable methods of targeting lifestyle factors such as PA and nutrition [44,45]. Using CBPR principles, we implemented and designed this mixed methods pilot study of PA-monitoring technology in collaboration with a CAB, the D.C. CHOC, established in 2012 prior to our large-scale study, the Washington, D.C., CV Health and Needs Assessment. The D.C. CHOC is comprised of a diverse group of community partners and collaborators (six church communities, church leaders, health care providers, leaders from nonprofit organizations, higher education, and local government) to consult on the planning and implementation of the assessment, and the interpretation and dissemination of study findings. Our CAB is a long-term partnership involved in both the CV Health and Needs Assessment and the design and implementation of future community-based behavioral weight loss interventions.

Consistent with CAB responsibilities to represent community members and their input in research activities and "identify key issues for action and strategize next steps" [46], the D.C. CHOC recognized the need to gain insight from and enhance understanding of the targeted community before developing an intervention. Therefore, they recommended a focus group and pilot study to test the acceptability and feasibility of the new PA technologies to be used in the large-scaled study. This step would not have been considered without a CBPR framework, thus demonstrating that novel ideas originate when research questions stem from community partnerships in the local context.

Our mixed methods pilot study revealed that community engagement is a critical component of community-based intervention development, as it allows for testing specific elements of an intervention that otherwise would be challenging without community support. Integrating a technology-based intervention in resource-limited communities requires researchers to first understand the community's technology environment and barriers to usage. If adequate knowledge is not obtained during the preliminary intervention development stages, interventions run the risk of being initiated prematurely and out of context. Engaging community members during the pilot study and focus group resulted in community-specific suggestions and improvements that we implemented in our large-scaled CV Health and Needs Assessment and plan to implement in a future behavioral weight-loss intervention. By engaging community members, we tailored the PA-monitoring technology to the specific community context. Our study showed that community insight within the CBPR framework allows for a research team to anticipate the community's future technological needs for an intervention.

CBPR methods also allowed us to tailor the implementation of our PA-monitoring system to the unique needs of the community members. Previous work suggests that behavioral weight loss interventions in African American, church-based settings can be effective if specific PA tools that promote weight loss are provided [47]. Before integrating such tools into an intervention, it is necessary to determine if the tools are feasible and acceptable for personal PA-monitoring in community-based populations. By engaging community members, we were able to gain insight into the strengths and weaknesses of our proposed PA-monitoring system. In particular, the focus group feedback enabled us to enhance our training and larger implementation (eg, identified hub point-persons, expanded hub hours), to address concerns (eg, wristband irritation, wristband falling off), and to clarify vague instructions (eg, vigorous activity definition, colored-light system). Our study demonstrates that incorporating CBPR principles is a necessary step during intervention development, especially when introducing technology-based PA-monitoring systems to resource-limited communities. This is particularly relevant for larger-scaled studies stemming from this pilot study, as CBPR research shows that incorporating community members' feedback enhances the relevance of a study, may improve sustainability of the proposed intervention, and may potentially improve the retention of study participants [44,45,48].

mHealth Technology Is Feasible for Physical Activity Interventions in Resource-Limited Communities

Our study has shown that, though certain challenges do exist, a wrist-worn PA monitor could be an mHealth tool used to monitor and facilitate PA for weight management in resource-limited, community-based settings. Recent work has demonstrated the effectiveness of eHealth and mHealth interventions for weight management; however, little is known about the success of mHealth PA interventions in community-based populations, particularly those that are resource-limited [45]. It is known, however, that the once wide "digital divide" (ie, the gap in computer and Internet access across racial/ethnic minorities) is narrowing due to the expansion

of mobile computing options [49]. As mobile phone usage increases, so too does the use of mHealth technology for health tracking [39,50].

Personal mobile devices offer a platform for health tracking and an opportunity to minimize costs and burden for the individual. Preliminary evaluation studies show that wearable devices (in addition to mobile phone step-tracking apps) accurately measure step counts when compared to manually and accelerometer counted steps, a finding that may alleviate reservations regarding mobile phone apps and wearables for PA monitoring [12]. In our study, participant PA data were successfully captured by the PA-monitoring system on the majority of days and monitored by the participant. For syncing and self-monitoring PA, participants with mobile phones preferred alternative options; such as a mobile phone app. Future studies should expand on this work by providing convenient and accessible options for syncing PA data in the community and on personal devices, as it may facilitate success and sustainability of wearable PA tracking in community-based settings.

Strengths and Limitations

Strengths of this study include the community-based, resource-limited nature of our setting, the novel use of technology with a community-based population, the incorporation of CBPR strategies, and the combination of qualitative and quantitative data gathered from the pilot testing. However, limitations of this study must be acknowledged. The study was short, limiting testing of participant adherence, engagement, retention, and attrition. Future work would benefit from a longer study period to gauge these factors. Additionally, generalizability may be a concern, as the sample size was small, and participants were recruited from the same African American, faith-based communities that would be targeted in a follow-up observational study. Additionally, while all subjects were African American, it is important to note that most had high levels of education, so study findings also would not be generalizable to a population with low levels of education. Future work would benefit from extension of this study to a larger and more diverse sample. Preferences and suggestions made in the focus group may not be representative of the target population, as responses were gathered in a group setting, with no opportunity to provide confidential responses.

While our study captured feasibility and acceptability of a potential technology-based tool for objectively capturing PA, our study did not intend to test the effectiveness of the PA-monitoring technology in modifying behavior. Future research should also include effectiveness in the study outcomes. While there has been progress incorporating technology in community-based PA interventions, more work, particularly around mobile device access and usage, digital literacy, and locations of publically accessible wireless Internet connections, is needed to improve our understanding of potential technology-based interventions in resource-limited communities. While the proposed PA-monitoring system used in this study allowed for assessing preliminary feasibility and acceptability, it does present limitations in the context of dissemination and implementation across diverse settings. As popular, commercially available PA-monitoring devices such as the Fitbit continue to advance, more accessible and affordable options will likely emerge that may support widespread implementation across diverse, low-resource communities more adequately than this study's proposed system.

Conclusions

A wrist-worn PA-monitoring system appears to be a feasible and acceptable technology for potential use in larger-scaled studies in community-based, resource-limited settings. CBPR methods, particularly CABs and focus groups, aid in early identification of issues, suggestions, and preferences as they relate to technology implementation in community-based, resource-limited settings. Additional work is needed to evaluate the effectiveness of and engagement with PA-monitoring systems in this setting. While a multifaceted behavioral intervention combining behavior change elements, dietary therapy, and PA is likely needed for weight loss management, this study provides evidence to support use of PA-monitoring technologies as part of a PA intervention in larger scaled studies in resource-limited, community-based settings in Washington, D.C. Of equal importance, this pilot demonstrates that in an era of limited funding and widening health disparities, we can ill afford not to engage the community leaders and community members in partnerships where clinicians, researchers, and community members can leverage the strength of their collaboration to design and implement health behavior studies that are both feasible and acceptable to the communities they target.

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Authors' Contributions

LRY carried out the quantitative analysis and drafted the manuscript. ATB participated in the design of the focus group, contributed to the qualitative analysis, and helped to draft the manuscript. GRW participated in the design of the focus group, drafted the moderator's guide, moderated the focus group, and contributed to the qualitative analysis and the drafting of the manuscript. MM and RC-M participated in the design of the focus group and contributed to the qualitative analysis. VM and JNS participated in study coordination. MP-L, TDJ, KLW Jr., KEC, and AAJ participated in the study design and coordination and participant recruitment. APG and LAG participated in the study design and coordination. TMP-W conceived of the study and led design and coordination, contributed to the qualitative analysis, and led in drafting the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Focus group Moderator's Guide- Cardiovascular Health and Needs Assessment Qualitative Study, 2014.

[PDF File (Adobe PDF File), 74KB - mhealth_v4i2e38_app1.pdf]

Multimedia Appendix 2

Criteria for judging scientific rigor in qualitative research.

[PDF File (Adobe PDF File), 42KB - mhealth_v4i2e38_app2.pdf]

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Abbreviations

app: applications
CAB: community advisory board
CBPR: community-based participatory research
CV: cardiovascular
CVD: cardiovascular disease
D.C. CHOC: D.C. Cardiovascular Health and Obesity Collaborative
eHealth: electronic health
mHealth: mobile health
NIH: National Institutes of Health
PA: physical activity
PMI: Precision Medicine Initiative

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Original Paper

The Electronic Patient Reported Outcome Tool: Testing Usability and Feasibility of a Mobile App and Portal to Support Care for Patients With Complex Chronic Disease and Disability in Primary Care Settings

Carolyn Steele Gray[1,2], MA, PhD; Ashlinder Gill[1], HBSc, Phd(c); Anum Irfan Khan[1], MSc; Parminder Kaur Hans[2], MBA; Kerry Kuluski[1,2], MSW, PhD; Cheryl Cott[3], DipPT, BPT, MSc, PhD

[1]Institute of Health Policy, Management and Evaluation, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

[2]Bridgepoint Collaboratory, Lunenfeld-Tanenbaum Research Institute, Sinai Health Systems, Toronto, ON, Canada

[3]Department of Physical Therapy, University of Toronto, Toronto, ON, Canada

Corresponding Author:
Carolyn Steele Gray, MA, PhD
Institute of Health Policy, Management and Evaluation
Dalla Lana School of Public Health
University of Toronto
155 College St.
Suite 425
Toronto, ON, M5T 3M6
Canada
Phone: 1 4164618252 ext 2908
Fax: 1 4164610656
Email: csteele@bridgepointhealth.ca

Abstract

Background: People experiencing complex chronic disease and disability (CCDD) face some of the greatest challenges of any patient population. Primary care providers find it difficult to manage multiple discordant conditions and symptoms and often complex social challenges experienced by these patients. The electronic Patient Reported Outcome (ePRO) tool is designed to overcome some of these challenges by supporting goal-oriented primary care delivery. Using the tool, patients and providers collaboratively develop health care goals on a portal linked to a mobile device to help patients and providers track progress between visits.

Objectives: This study tested the usability and feasibility of adopting the ePRO tool into a single interdisciplinary primary health care practice in Toronto, Canada. The Fit between Individuals, Fask, and Technology (FITT) framework was used to guide our assessment and explore whether the ePRO tool is: (1) feasible for adoption in interdisciplinary primary health care practices and (2) usable from both the patient and provider perspectives. This usability pilot is part of a broader user-centered design development strategy.

Methods: A 4-week pilot study was conducted in which patients and providers used the ePRO tool to develop health-related goals, which patients then monitored using a mobile device. Patients and providers collaboratively set goals using the system during an initial visit and had at least 1 follow-up visit at the end of the pilot to discuss progress. Focus groups and interviews were conducted with patients and providers to capture usability and feasibility measures. Data from the ePRO system were extracted to provide information regarding tool usage.

Results: Six providers and 11 patients participated in the study; 3 patients dropped out mainly owing to health issues. The remaining 8 patients completed 210 monitoring protocols, equal to over 1300 questions, with patients often answering questions daily. Providers and patients accessed the portal on an average of 10 and 1.5 times, respectively. Users found the system easy to use, some patients reporting that the tool helped in their ability to self-manage, catalyzed a sense of responsibility over their care, and improved patient-centered care delivery. Some providers found that the tool helped focus conversations on goal setting. However, the tool did not fit well with provider workflows, monitoring questions were not adequately tailored to individual patient needs, and daily reporting became tedious and time-consuming for patients.

Conclusions: Although our study suggests relatively low usability and feasibility of the ePRO tool, we are encouraged by the early impact on patient outcomes and generally positive responses from both user groups regarding the potential of the tool to improve care for patients with CCDD. As is consistent with our user-centered design development approach, we have modified the tool based on user feedback, and are now testing the redeveloped tool through an exploratory trial.

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KEYWORDS

eHealth; mHealth; multimorbidity; primary care; usability; feasibility; pilot

Introduction

Background

People experiencing complex chronic disease and disability (CCDD) face some of the greatest challenges of any patient population. Patients with CCDD can be characterized as having multiple chronic conditions that impact on their daily lives [1], they are at a higher risk of experiencing poor health outcomes [2,3] and will tend to use health services more than patients with single conditions [4]. These patients are considered to be among the highest cost patient populations in the health care system [2]. Health systems worldwide are examining ways in which care can best be structured to meet the needs of this growing, complex, and high-cost population.

Beyond the challenges that patients face in managing their own illnesses, primary health care providers struggle to manage the multiple conditions with discordant competing symptoms faced by these patients [5] and lack appropriate clinical practice guidelines to guide decision-making [6]. Patient-centered care, which allows for an individualized and holistic approach to patient care, is viewed as crucial to address the highly variable needs of patients with CCDD [7-10]. Patient-centered care can be supported through the adoption of goal-oriented care approaches as a means to help patients prioritize competing issues [11]. However, goals are often not agreed upon between patients with complex care needs and their clinicians [12], and clinicians may consider the process of ascertaining goals to be "too complex and too time consuming" [13].

The electronic Patient Reported Outcome (ePRO) mobile app and portal system were developed to support patients with CCDD and their primary health care providers to collaboratively set and monitor health-related goals. Mobile health (or mHealth) and other eHealth technologies have been previously used to help track health status and monitor symptoms via telemedicine and wearable technologies [14-17] and encourage improved engagement and changes in health behaviors by patients [18,19]. Although there are tools available that help support goal setting and monitoring, most of these are disease-specific (eg, supporting patients with diabetes [20]), and there are few available tools that can address the needs of patients with complex care needs who tend to be high users of the health care system [21].

Development of the ePRO tool was done in collaboration with the technology company, QoC Health Inc. QoC Health Inc. is a Canada-based technology company that is focused on developing patient-centered technology to enable shifting care for patients to the community [22]. The ePRO tool was developed and tested through an iterative user-centered design approach [23]. As a part of this development strategy, conducting usability and feasibility testing is vital to ensure that tools are understandable and can be adopted by target users in typical settings before running larger more costly evaluations [24,25]. This study describes findings from a pilot study to test the feasibility and usability of the ePRO tool from the perspective of patients with CCDD and health care provider users from a primary health care practice in Toronto, Ontario, Canada.

Feasibility and Usability Framework Guiding Study and Analysis

The aims of this study were to: (1) determine whether the ePRO tool was feasible to be used by patients with CCDD and their primary health care providers as part of the delivery of primary health care services and (2) assess the usability of the ePRO tool from the perspective of both patient and provider. Our emphasis was on exploring these questions in a real-world setting, and as such, we adopted a pilot study approach in which patients and providers used the tool over a 4-week period.

We used the "Fit between Individuals, Task and Technology" (FITT) framework to guide our feasibility and usability assessment [26,27]. The FITT framework suggests that adopting new eHealth systems requires a fit between the user, the technology, and the task or process that is undertaken. Feasibility refers to the ability of users to adopt a technology or intervention in daily routines (often assessed through use of the tool [28]), which is strongly related to the FITT model intention to assess the ability of a technology to be adopted. Usability specifically speaks to how the technology is meeting user needs and tasks. As such, the FITT framework was adopted to assess feasibility overall, with an embedded usability analysis to assess the technology specifically (see Table 1). Tools are typically assessed in terms of efficiency (what resources are required by the user to complete tasks [27]), effectiveness (the ability to complete tasks completely and accurately), learnability (how easily users can learn the system), and user satisfaction with the product [27,29,30]. Using this framework, we sought to answer the following research questions: (1) *Is the ePRO tool feasible to be adopted into inter-disciplinary primary health care practices?* and, (2) *is the ePRO tool usable from both the patient and provider perspective?*

Table 1 summarizes an overview of indicators used to assess feasibility and usability factors. These measures are aligned with similar studies of usability and feasibility [27,29-31]. As is typical in many feasibility and usability pilots, we relied on a relatively small sample size of patients and providers to test

the ePRO tool. Although some usability studies have used surveys such as the System Usability Scale [32] or the Post-System Usability Questionnaire [24], given our small sample, we opted to capture most data through qualitative focus groups, interviews, and observational notes. Quantitative data regarding system use were pulled directly from the ePRO system data (ie, information generated from the technology system itself) to capture compliance and adherence information. Qualitative data collection and analysis allowed us to capture the breadth and depth of user experience.

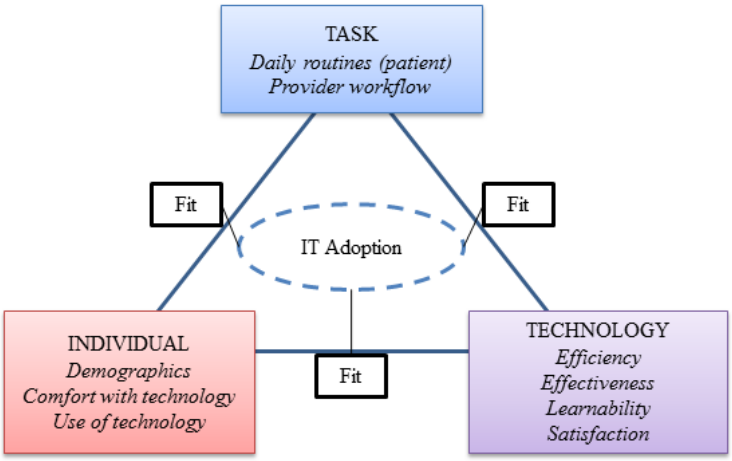
Table 1. Feasibility and usability measures.

Conceptual framework		Measure	Data source
Feasibility			
	User	Demographics	Patient information form
		Comfort with technology	Patient and provider self-report (in training or in focus groups or interviews)
		Use of technology	Data of ePRO system
	Task	Fit into daily routines	Patient focus groups and interviews
		Fit into provider workflows	Provider focus groups
	Technology	Usability assessment (in the following category)	
Usability			
	Efficiency	Time to complete monitoring (ie, time on task)	System data
		Reported efficiency	Patient focus groups and interviews Provider focus group
	Effectiveness	Reported errors	Online *issue tracker* system to communicate errors and problems with the system to QoC Health
	Learnability	Reported learnability	Patient focus groups and interviews Provider focus group
	Satisfaction	Reported satisfaction	Patient focus groups and interviews Provider focus group

Figure 1 presents a diagram of the FITT framework based on Sheehan and colleagues [27] original FITT model which includes the measures used to capture the components of the framework in our study.

In a usability and feasibility assessment, we could have also explored privacy and security issues related to the system [33]. Given our systems are fully compliant with all privacy and security legislation related to transmission of patient data in Canada and the United States, and we had captured patient and provider perspectives on privacy and security in earlier stages of development [34], we did not believe it was necessary to assess privacy and security again at this stage of testing.

Figure 1. A diagram of the FITT Framework to assess usability and feasibility. Adapted from Sheehan et al [27] p. 364.



Methods

Setting

The ePRO tool has been developed within a Toronto-based Family Health Team (FHT); an inter-professional team of providers delivering primary health care services [35]. Patients have a lead primary care provider, either a physician or nurse practitioner; however, patients may receive care from any provider in the team (registered nurses, a social worker, a dietitian, and diabetes nurse educator). Six providers from the team participated in the study as *active ePRO* providers including 1 physician, 1 social worker, 1 registered nurse, 1 dietitian, and 1 diabetes educator. *Active ePRO providers* were involved in goal setting and monitoring of patients at the start of the pilot study and conducted at least 1 follow-up visit with the patient to overview progress using the portal system. Other providers, although not actively participating in the study had the opportunity to view their patient's data on the portal at any time if they chose.

Recruitment

Active ePRO providers were asked to individually identify 3-5 eligible participants from their practice panels. Eligible patients met all the following inclusion criteria: (1) An FHT patient on the participating provider's practice panel; (2) physical capability to use a tablet or availability of a caregiver who had the physical capability to use a tablet who could enter data on the patients' behalf; and (3) had complex care needs (2 or more chronic conditions, identified difficulty managing conditions, and social complexity and/or mental health issues) as identified by providers. Potential participants were contacted directly by FHT administrative staff over the phone or when they checked in for their appointment to ask if they were interested in being contacted by a member of the research team at which point they were informed about the study, what would be required for participation, the consent process, and information on privacy of their information. The recruitment process lasted from October 6, 2014 until November 7, 2014; during the process, 12 potential participants were identified. Eleven of the participants could be reached and agreed to participate.

Participants provided informed consent by signing consent forms at the time of training and orientation on the device. Participants also filled out patient information forms at this time to provide us with data on patient demographics. Participants were assured that their participation was voluntary, their personal data would only be accessible by the research team, and he or she could return the device at any time if they became ill or were having difficulties monitoring their goals. All the participants were assigned a unique identifier to ensure their anonymity before data analysis. Online data submitted from the device were on a secure server hosted by QoC Health Inc. The server is compliant with all health information data and security laws applicable in Canada and the United States. The technology partner, who had access to patient data needed to provide technical support, signed a confidentiality agreement before the initiation of the study.

Full ethics approval for this study was obtained from the Joint Bridgepoint Hospital-West Park Healthcare Centre-Toronto Central Community Care Access Centre-Toronto Grace Health Centre Research Ethics Board before the initiation of the study.

Training

Providers were trained in 2 separate 1-hour group training sessions before the initiation of the pilot study, one session for *active ePRO providers* and another for other providers, mainly physicians from the practice, in the event they wanted to monitor their patients involved in the study. Patients were trained one-on-one with a member of the research team in a 30-minute session at the time when consent was given to participate in the study. Although providing training to users limits our ability to test learnability, patient and provider users required a baseline level of understanding of the tool's functionality and capabilities to appropriately engage in the tool, allowing us to test other key aspects of feasibility and usability. We anticipate that for this tool to be used as part of regular practice, both providers and patients would require some baseline training; as such, including training in our study offers a closer approximation to real-world use.

The Intervention: Overview of the ePRO Tool

The ePRO tool includes 2 key features: (1) My Goal Tracker and (2) Hospital CheckOut.

Feature #1: My Goal Tracker

The My Goal Tracker feature allows patients and providers to collaboratively identify patient goals and help patients to track outcomes related specifically to those goals. In the development of the ePRO tool, providers indicated that they engaged in goal setting activities with their patients with CCDD as a means to support improved self-management [36]. Activities such as motivational interviewing, counseling, and health coaching are used by providers to help patients manage at home between visits. The tool allows patients and providers to set goals related to 5 different areas identified as most important by patients with CCDD, their caregivers, and their primary care providers in the earlier phases of development. These areas include: (1) maintaining or improving general physical and social well-being (physical health goal); (2) maintaining or improving general mental well-being (mood and memory goal); (3) maintaining or improving mobility (mobility goal); (4) pain management (pain goal); and (5) weight management (diet goal).

Monitoring protocols are linked to each of the 5 goal areas and drawn on the basis of 3 valid and reliable generic outcome measures developed by Patient-Reported Outcomes Measurement Information System (PROMIS). The 3 PROMIS tools that are included are: (1) The General Health Scale; (2) The Pain Interference Scale; and (3) The Health Assessment Questionnaire. The PROMIS tools used in the monitoring protocols are generic rather than disease-specific patient-reported outcome measures to better reflect our patient population of interest. Furthermore, these tools have demonstrated validity and reliability in chronic disease populations [37-39]. Note that the diet goal was not based on a PROMIS tool but rather allowed patients to take pictures of their food and track their weight.

Feature #2: Hospital CheckOut

The Hospital CheckOut features allow patients to inform their primary care provider when they have visited and been discharged from a hospital. This feature addresses significant communication challenges identified by patients and providers through a user-needs assessment conducted in the first phase of our tool development [34].The patient simply enters the date of discharge, reason for visit, and name of hospital, and an alert is sent to the provider so that they can reach out to the hospital and retrieve the discharge report.

The Portal System

The provider portal allows providers to set up *care plans* with patients, which identify on which goals patients will be working toward. Once added to a patients' Care Plan, the goal shows up on the patients "My Goal Tracker," and the patients then can track their progress toward their goal over time on their mobile device or on the patient portal. The provider is also able to view the Hospital CheckOut alerts on the portal. The patient portal allows patients to view their progress over time. Patients can also choose to enter their monitoring data on the portal rather than on the mobile device if they choose. In general, the portal system was intended to be more heavily used by providers when setting up goal tracking and viewing patient tracking, with patients only needing to access the portal to view their own results; all data tracking activities for patients can be conducted on the mobile app. See Figure 2.

Figure 2. Depiction of the ePRO portal.

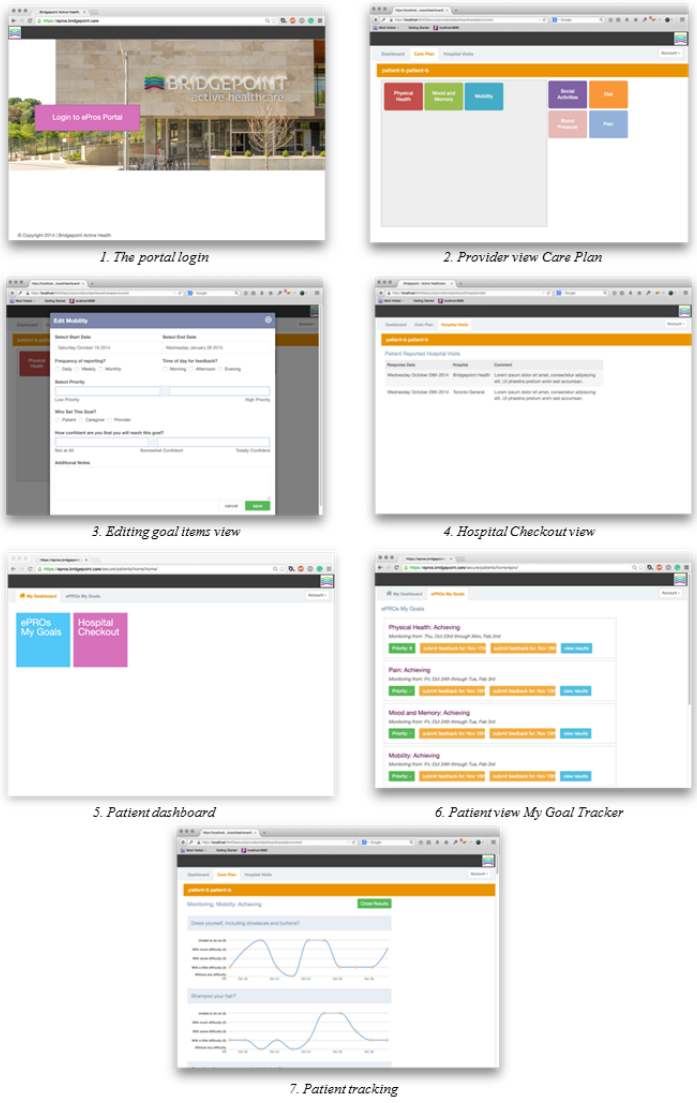
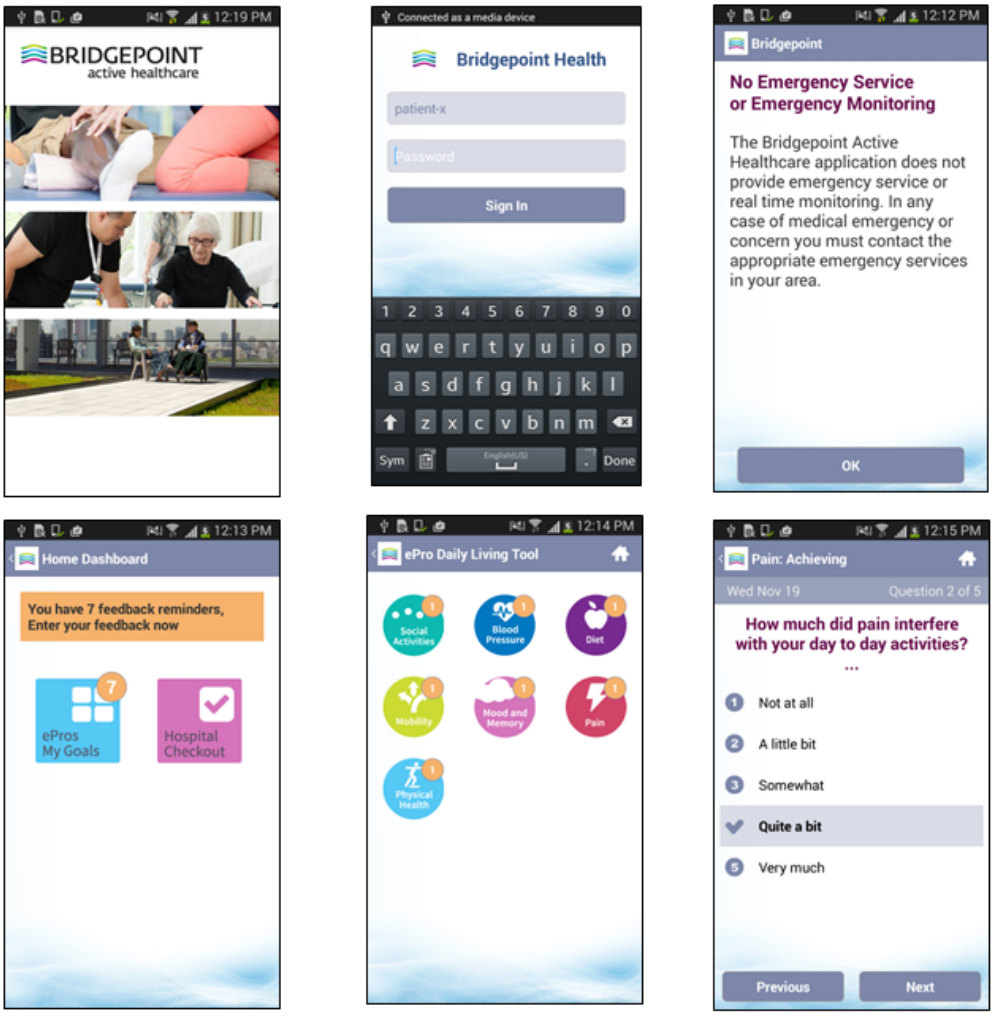


Figure 3. Depiction of the ePRO mobile app.



(Top row left to right): Open page; login; No Emergency Service notice
(Bottom row left to right): Dashboard; care plan; tracking question

The Mobile App

The mobile app allows patients to track their goals and report hospital visits using the Hospital CheckOut. For the pilot study, patients were provided with locked Samsung Galaxy II android phones with the ePRO app uploaded. As the device was locked, they could only use the ePRO app on the phone. All devices were supported through a fourth generation/long-term evolution connection to not only allow patients to update their data at any time but also allowed the QoC Health Inc. to push bug fixes as required. See Figure 3.

Pilot

After training, patients worked with providers to collaboratively identify goals and then add them to their care plans. This discussion occurred during a 30-minute appointment, which is typical for allied health professionals working with patients with CCDD to identify goals and improve self-management. Patients then tracked their goals for a 4-week period, after which they returned to their provider to view and discuss their results and tracking. Some patients visited their providers more frequently during the course of the study, which was part of their usual care. For instance, patients visiting the social worker typically visit the social worker once a week, and at each visit, they would discuss goal tracking and modify treatment plans and goals as needed.

At the end of the 4-week pilot study, patients and providers were asked to participate in separate focus groups where they provided feedback on the feasibility and usability of the tool. The patient focus group was held on December 17, 2014 (n=5), and the provider focus group was held on January 22, 2015 (n=6). Three patients who completed the study but were unable to participate in the focus group in December were separately interviewed to gather their feedback on usage of the tool. System data regarding all patient-reported data, types of goals tracked, response counts, time on the system (both patients and provider), and number of times the system was accessed were pulled by QoC Health Inc. and given to the research team in Excel format for analysis, and in addition, they provided an overview report of system use.

Analysis Method

Basic descriptive statistics were conducted using the system data. Content analysis of data from the issue tracker system was conducted to identify errors reported by users. Focus groups

and interviews were analyzed using thematic content analysis [40]. Common themes were identified by 2 different groups of authors, for the patient (AG, AIK, and CSG) and provider (AG, PH, and CSG) focus group data. The authors reviewed the transcripts independently and developed their own preliminary coding scheme. Multiple iterations of coding occurred until consensus was reached on themes among reviewers to develop a final coding scheme [40]. To help organize themes as per the usability and feasibility framework summarized in Table 1, authors (AG and AK) identified coded themes that captured components of the feasibility framework for analysis. Qualitative data management software, NVivo9 [41] was used to manage the data after a final coding scheme was created. Using NVivo 9, researchers code text by highlighting text and selecting the appropriate code from the coding scheme. Coding was conducted by authors (AG, PH, and AIK), and coding reports from NVivo, in which all examples of data attached to a particular code, were generated and reviewed by the lead author along with AG, PH, and AIK to ensure content fit within the definition of the code.

Four patient participants and all providers were willing to provide feedback on the findings (member checking). These individuals were sent packages that included an overview of the analysis and a form to provide feedback. No feedback was returned from patients (1 letter was returned from a patient as the address provided by the participant was incorrect), 2 forms were returned by providers agreeing with findings.

Results

Assessing Feasibility: Understanding Users and Tasks

Patient User and Tasks

Twelve individuals were identified by providers as potential participants, among them, 11 were successfully contacted by the research team. Participants were both medically and socially complex; they had 2 or more chronic conditions (reported conditions include: diabetes, mental illness, joint conditions, heart conditions, kidney conditions, and chronic pain) and social vulnerabilities (ie, at least 2 of them were in low-income housing; however, socio-economic status was not explicitly captured). Two participants dropped out within the first few days due to health issues, and a third participant dropped out of the study after 2 weeks due to increased anxiety associated with the need to report on her health and using the mobile device. This patient already had high levels of anxiety and depression (including anxiety related to using their personal iPhone) before the initiation of the study. The provider anticipated that this could occur but wanted to give the patient a chance to engage in something new as part of her ongoing treatment. Other studies have found that health monitoring may lead to adverse effects on mental health and well-being [42]. Five of the patients who participated in the full study participated in the focus group, and the 3 others provided feedback through interviews (2 of them over the phone and the remaining 1 patient in person with CSG). See Table 2 for an overview of patient users and their use of the ePRO tool during the pilot.

Table 2. Patient demographics, goal monitoring activities, and system usage.

Patient participants		N=11
	Average age	58 years
	Min	35 years
	Max	72 years
	Male	n=5
	Female	n=6
	Other (ie, transgender)	n=0
Country of origin		
	Canada	n=5
	United Kingdom	n=2
	United States	n=1
	Jamaica	n=1
	Not reported	n=2
Reported comfort with technology		
	Previous experience	n=6
	Little experience	n=2
	Not reported	n=3
Attrition		n=3
Goals tracked		
	Physical health	n=6
	Mood and memory	n=3
	Pain	n=2
	Diet	n=2
	Mobility	n=1
	Patients tracking 1 goal	n=4
	Patients tracking 2 goals	n=4
	Patients tracking 3goals	n=1
	Patients tracking 4 goals	n=1
	One dropout patient did not set a goal	
System usage		
	Unique survey completions	210
	Questions responded	1311
	Portal access	1.74 average
	(only accessed by 4) patients)	Min 0
		Max 3

Table 3. Time to complete monitoring tasks for patients.

Goals	No. of questions per survey/protocol	No. of protocol completions	Time to complete protocol (minutes)
Physical health	6 required, 3 optional	75	Average: 3 Min:1; Max:12 1 outlier: 1428[a]
Mood and memory	5 required, 3 optional	68	Average: 5.3 Min:1; Max:57 2 outliers: 1425 and 1180[a]
Pain	5 required, 3 optional	52	Average: 5.6 Min: 1; Max: 31 1 outlier: 1427[a]
Mobility	23 required, 2 optional	3	Average: 6.3 Min: 2; Max: 16
Diet	2 required, 1 optional	9	Average: 1.7 Min:0; Max:3 1 outlier: 683[a]

[a]If patients left surveys in the middle of completing them, the system recorded the full amount of time it took to complete the survey resulting in outliers as high as 1428 minutes.

Patients reported that they manage their multiple chronic illnesses, acute issues that arise, and personal issues as part of their daily lives. Patients also reported using other apps to help manage their health with activity apps and tools such as FitBit, JawBone, and blood sugar monitoring apps.

Provider User and Tasks

Active ePRO providers, differed in terms of profession and the role they played in the primary care practice; however, all engaged in goal-setting activities with patients before the initiation of the pilot study. Through training and piloting, it was clear that most of the provider participants had a strong competency with technology with only 1 participant identifying more limited capability. In general, providers work in a busy practice where they typically get 30 minutes with their patients, whereas the physician gets closer to 10 minutes. Providers accessed the portal much more often than the patients, on average 10.4 times over 4 weeks (min: 4, max: 15), which is understandable as patients later reported forgetting that there was a portal or experiencing errors with the portal.

Providers reported that they were primarily only able to view patient data just before a patient's follow-up visit to see a snapshot of the patient's progress between appointments as that fit more readily into their existing workflow. Some providers reported seeing patients weekly (as was the case for the social worker), and others saw patients more on an as-needed basis. Providers noted that they already engaged in goal-setting activities with their patients often using the SMART goal framework (used initially in rehabilitative settings, see [43]). The practice also provides chronic disease management programs (ie, smoking cessation program). All providers are required to chart all patient encounters in their electronic medical record (EMR).

Assessing Usability: Technology Assessment Efficiency, Effectiveness, and Satisfaction With the ePRO Tool

Patient Feedback

Efficiency

Although each protocol did not take long to complete (on average 2-6 minutes, see Table 3), patient participants found that data entry became a tedious task, and at least 2 participants noted that they began completing questions for multiple days at one time, potentially compromising the validity of the self-report data. The ePRO system data revealed that in fact 5 patients completed questions for multiple days at one time, which accounted for between 8% and 46% of the participants' answers. Participants also found that they forgot to do their monitoring when managing acute health issues or other life stresses. For example, one participant was managing chronic pain issues and lapses in her memory and experienced difficulty incorporating the device into her daily life.

> *And I don't think that the pain was the total cause of memory lapse but it had a great deal to do with it.I mean I was going through a great deal of stress. So when I started to add them all together, you know, the stress, the workload, the impending developments that were happening in my life in completely different areas, you know, it was just like I'm standing here trying to juggle 8 balls without having any of them touch the floor it has a tendency to make you forget about whatever else you're doing* [P009]

atients made a number of suggestions for creating a more responsive tool that would complement their daily routine through reminders (for patients to input their data) and feedback acknowledging their completion of questions, flagging results (as appropriate), and connecting with the other health monitoring apps (ie, FitBit, JawBone, blood sugar monitoring). The most common suggestion was to enable connections between their

health goals from the ePRO tool with other apps they were using to improve efficiency of their self-monitoring efforts.

> *Like linking with FitBit, for example... Yes, I think that would be very useful. Because your…well, it depends on how you use FitBit of course but, you know, you are tracking a lot of indicators around activity, weight, etc…. if you 're diabetic, is it to link your blood sugar to your performance? You know, all those kinds of things. I think it would have to have a specific reason for using it.*" [P002]

Effectiveness

Some patients in the study identified that they felt using the tool had an early impact on their ability to self-manage and track their health goals. The tool helped to catalyze a sense of responsibility over their care and helped to improve patient-centered care delivery.

> *I knew why I felt better one week and why I did not feel better the next week.* [P011]

> *[my provider and I] were able to see …that [my goal] was not moving really, and to try to change it better…* [P005]

Patients were able to reflect on their progress of achieving their goals with providers and valued this interaction.

> *When we were talking about my goal, we were going through the charts, her giving her opinion. She was actually changing my opinion of how I should have answered that question. Well, that should be more interactive. I'd like to get her to do that sooner.* [P012]

However, patients experienced technical errors and difficulty in reviewing previously entered open-text data. In addition, questions often did not appear at the correct times or days, and patients were unable to locate different features on the tool. One patient and provider were so frustrated by the errors that they nearly pulled out of the study. This particular patient called both the provider and research team frequently to troubleshoot connectivity issues and to discuss aspects of the tool they did not like.

Learnability

The learning process was also an important challenge as one-time training was not considered to be sufficient. Participants suggested that adding instructional videos to highlight the key steps for using the device might be beneficial for visual learners and easier to follow than written instructions.

Satisfaction

Once technical errors experienced in the first 2 weeks of the study were resolved, patients appreciated having a device to help them monitor their health goals and health behaviors.

> *I found it very easy to use. I found that once I determined when I was going to do it daily, that I did it. I always got it done* [P002]

However, some patients reported feeling isolated with the mobile device, and felt that the tool could become a replacement for inperson consultation.

> *I think the only concern that I had big time was that it might be used to replace people. And that would really sadden me. I think especially in this time and, you know, people do really need people-to-people care and contact. And especially when they're sick* [P003]

To mitigate feelings of detachment from the health care provider, participants suggested that having questions and goals that were more specific to the participant's conditions, as well as personalized feedback from the provider or peers from the clinic would be helpful. Tool-enabled feedback, particularly from peers, was also viewed as a way to offer encouragement on progress toward goal attainment by way of a shared experience.

Provider Feedback

Efficiency

The research team was unable to track the time it took for patients and providers to set up the goals and the monitoring regime. Providers would schedule a 30-minute session to complete this task; however, they reported that the actual use of the tool would not take the full 30 minutes, but often the conversation about goal setting with the patient would require the entire visit.

After the initial visit, provider participants reported experiencing difficulty incorporating patient data into their workflow in terms of: (1) increased charting time required to input data into the provider's EMR and (2) being able to view data in manageable chunks.

> *It would be very helpful if I can see that reporting for a week. Because what I did was I chose people that I see weekly anyway. But realistically in terms of workload even one patient, I bet I would not look at it, you know, every day.* [Provider 06]

Providers also identified a desire to have the content of the tool better aligned with current programs and practices. As one provider noted:

> *You know, in terms of using that in the template, that kind of way to set up and frame a goal with them... Because we're working with SMART goals, they need to be that specific...* [Provider 04]

Finally, some providers felt that they may be liable for monitoring patients during out-of-office hours, which would require additional time and resources. One provider discussed a specific experience during the pilot in which one of her two patients enrolled in the study started "sinking fast," which she was able to catch by reviewing monitoring data on the portal. However, the provider identified this may not be a scalable solution in future:

> *Oh my god, this guy is sinking fast, I better make the phone call. Which I did. But I can't do that for all my patients all the time.* [Provider 05]

Although it was made clear to providers and patients in training and on the app (see the "No Emergency Monitoring" message in Figure 3) that continuous monitoring was not available, some providers still reported experiencing conflict between ensuring

that the tool fit in their existing workflow and their desire to provide high-quality care to their patients. Over the course of the pilot providers, most of them reviewed data before the patient's appointment rather than monitoring in-between visits and found greater potential for the data to be useful as a synopsis of the patient's progress.

Effectiveness

Some providers noted that having the tool in front of them helped to focus the conversation on patient goals.

> *To be able to talk about this with her, it was like, oh, thank God I can help set a goal.*" [Provider 06]

However, providers had difficulties goal setting for some patients, as the goals on the tool were not specific to the health monitoring options on the tool. Providers expressed concerns that the tool's content was not comprehensive, as setting a specific goal and self-management were two different elements for chronic disease management:

> *Well, because we're diabetes educators, R2 and I, we set goals all the time. But the goals that we're setting were not reflecting in the options that were available. So there was no blood sugar. You know, there's no goal for blood sugar. There was no goal for pain management. There was no… Like there were n't specific… They weren't specific enough. And because we're working with smart goals, they need to be that specific.* [Provider 05]

To improve effectiveness (and efficiency), providers wanted the tool to fit better with their existing workflows and programs, for example, through better alignment with creation of SMART goals for patients or allowing for monitoring protocols that aligned with goals of existing chronic disease management programs.

Providers experienced technical issues with the device and Web portal, including data not appearing on the portal after being entered on the mobile device, goals not showing up on patients' devices after being set up on the portal, and some challenges with login.

Learnability

Providers were unsure of where in the tool to enter free text and how to locate specific goals within the tool. In the focus group, providers noted forgetting about certain elements of the tool, suggesting the need for a manual or additional training sessions.

Satisfaction

Although providers also recognized the value of the tool in assisting the patient to self-monitor their chronic conditions, self-monitoring and goal attainment were two aspects in which the tool was felt to be lacking. For example, one provider discussed his or her goal of helping improve the patient's mood and using the tool to monitor the patient's eating habits and how the tool offered limited utility in supporting that goal.

> *The mood one might be a good pre and… Like I do n't know, it depends on what the goal is. But like maybe a pre and post, doing the study to get like a sense of where they are before and where they are after. But like again with like eating the piece of fruit, her answering those questions every day, I do n't know, maybe she gave you feedback saying that was really helpful, I do n't know. I didn't think it was all that helpful. At least it wasn't helpful from my perspective.* [Provider 04]

With regard to goal attainment in particular, providers were concerned that questions were not specific enough to match goals.

FITT Assessment of the ePRO Tool

The technology assessment (efficiency, effectiveness, learnability, and satisfaction with the tool) was compared with identified user needs and tasks. This analysis is summarized in Table 4 to provide an assessment of the feasibility and usability of the ePRO tool.

Table 4. Feasibility and usability assessment overview.

	Users	Task	Technology
Patients	Multiple chronic conditions with moderate comfort with technology. Interests in monitoring goals related to physical health, mood and memory, pain, diet, and mobility Primarily used the mobile device	Daily routines: • Have multiple health and personal concerns to manage • Some already using other self-management support tools and apps	The ePRO tool met user needs to monitor and track goals they wished to work on; however, it did not fit well with daily tasks given questions were repetitive and not appropriately tailored to goal activities, and the tool was unable to connect with other monitoring activities in which patients were already engaged.
Providers	Multi-disciplinary providers from primary health care practice, moderate to high level of comfort with technology. Busy practice with limited time to monitor patients between visits. General interest in helping patients better manage	Workflows: • Only able to review data before visit to get a snapshot view of the patient, limited time to monitor patients in-between visits • Use SMART goals • Need to chart in EMR systems	The ePRO tool was helpful in getting patients to discuss goals as a strategy to improve management; however, it did not fit well with provider workflows in terms of supporting SMART goal development and integration with the EMR.

Discussion

Despite the many challenges, patients and providers demonstrated near-daily use of the device over a short period of time. When we explore some of the more detailed feedback from the focus groups, ease of use of the tool, the noted impact on ability of patients to self-manage and patient-centered care delivery, and the potential for the tool to improve on their sense of responsibility over their care, may be the reason why there was daily usage among patients and weekly usage among providers despite challenges. Providers were equally positive about the potential of the tool to improve efficiency and patient-centeredness at the point of care, particularly if suggested changes were to be implemented.

However, based on our assessment criteria, overall feasibility and usability of the tool are determined to be low from both the patients' and providers' perspectives. Concerns regarding the impact on patient-provider relationships, the repetitive nature of questions leading to individuals filling out multiple questions at one time, and an inability of the system to connect with other monitoring activities they were already doing (eg, physical activity monitoring using other apps and devices) were among the more notable issues identified. Furthermore, the system was plagued by connectivity errors, which caused ongoing concerns and frustrations for both patient and provider users. Errors in usability tests are not uncommon and have been noted to impact on usability [17]. We should also consider that daily data entry may be too frequent for most users, and as such, looking for ways to collect data unobtrusively (eg, through connecting to a FitBit or JawBone device) may not only meet identified user needs but could also serve to reduce respondent fatigue.

Providers had a difficult time integrating the monitoring into their daily workflows. Although these providers were already doing goal setting with patients, concerns with a lack of integration with their EMR system and content that did not follow their usual model of care made usability and feasibility of the ePRO tool challenging. A notable concern is how the use of standardized monitoring protocols did not allow for effective monitoring of patient goals, which speaks to a relatively poor task-technology fit. Although the PROMIS tools are valid and reliable measures, these types of generic outcome measures are less helpful for day-to-day management of health-related goals for patients with CCDD. The adoption of valid and reliable patient-reported outcome measures thus may not be as useful in ongoing management of patients with CCDD and patient-centered care delivery [44] but rather may be more useful to assess whether goal attainment is having an effect on outcomes over the medium to long term (6-12 months).

Workflow integration is an important consideration as the introduction of technologies not only augments work processes but in fact reorganizes them [45]. Coupling ehealth tools successfully to health care provider workflow is challenging. Heterogeneity of care practices paired with interdisciplinary team roles and responsibilities, as with our FHT providers, makes it increasingly difficult to accurately and consistently predict provider care needs, especially when caring for patients with complex care needs [46-48]. However, the appetite for mobile health solutions that match provider workflow is in demand [49], with the likelihood of meaningful adoption increasing when end users are involved in the design process [50].

Unfortunately, the tool did not support interdisciplinary practice as we had hoped. We had anticipated that data could be used by the entire FHT (not just the active providers) to help in management of patients; however, the tool did not get used in this way during the pilot study, rather, providers used data in their own management of patients as part of their solo practice. Four weeks may have been a too short period, and potentially, longer term use may provide more opportunities for the data to be used by the interdisciplinary team. The impact on interdisciplinary practice will be examined in our exploratory trial (4-month trial) and pragmatic trial (12-month trial) of the ePRO tool.

The low usability of the tool was a somewhat surprising finding given the extensive user-centered design approach used in the earlier phases of this study. Providers from the FHT as well as patients and caregivers provided detailed and ongoing feedback on the development of the tool (outlined in [36]) before running the usability pilot; however, many of the usability and feasibility challenges experienced in the pilot presented here, particularly those with regard to content, were not identified in earlier stages of development. Typical user-centered design approaches may face challenges when addressing particularly complex patient populations, such as children and those with cognitive impairment, and user feedback may not be useful in all phases of the design process due to the lack of necessary design skills in users [51]. More than likely, however, was that the challenges experienced were not foreseen, and as such reinforced the importance of conducting small, real-world setting pilots such as those presented here as part of a user-centered development approach.

Limitations

Quantitative data on usage pulled from the ePRO system data did not provide the level of detail we would have liked with regard to tool efficiency. We had made a deliberate decision to do a real-world pilot test of the tool rather than test usability in a laboratory setting as has been used in other usability tests [52]. Although limiting, we dictate that real-world usability testing was more valuable when developing tools for a diverse user group such as patients with CCDD and multidisciplinary providers. Future testing will seek to refine the data that can be collected from the ePRO system to be able to extract time data more effectively. Another limitation of our study was the attrition rate of the patient participants. One of the challenges working with patients with CCDD means that health issues may impede ongoing participation in research. Future piloting and evaluation work will seek to oversample to a greater extent to offset likely dropouts.

Although the numbers of test users are low in our study, Nielsen and Landauer's [53] model of detecting usability problems suggests that most usability problems (75%) can be detected by 10 users, and 50% of them can be detected by as few as 5. Furthermore, they offer a cost-benefit analysis of including additional users in testing and suggests that an optimal number

of test subjects in medium-large projects is 6.7 when using test users to conduct a usability assessment. As such, although our numbers are low, they are aligned with other similar usability studies [30,31,54-57] and also allow us to capture most usability problems we are likely to see.

Finally, we were only able to conduct focus groups and interviews after the pilot study rather than during the study. In a similar pilot, Verwey et al [17] interviewed each user directly after all consultations to capture usability information, which may allow for capturing more useful data.

Conclusions and Future Works

Although our study suggests relatively low usability and feasibility of the ePRO tool, we are encouraged by the early impact on patient self-management and patient-centered care delivery as well as the general positive response from patients and providers regarding the importance and potential of a tool, which supports goal-oriented care delivery for patients with CCDD in primary health care settings. Findings from the pilot will be used to modify the ePRO tool to improve its feasibility and usability. Key considerations moving forward include: modifying goal monitoring protocols to allow for tailoring to specific goals, ensuring that we target patients with CCDD who could benefit most from goal-oriented care and prescreening for those who may be likely to experience anxiety related to participation, integrating the system into the EMR or with provider workflows, enabling integration with external apps used by patients (eg, JawBone or FitBit), and providing ongoing training opportunities potentially embedded within the tool (ie, through videos and walk-throughs).

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Conflicts of Interest

None declared.

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Abbreviations

CCDD: complex chronic disease and disability
EMR: electronic medical record
electronic medical record: electronic Patient Report Outcomes
FITT: fit between individuals, tasks, and Technology
IT: Information Technology
PROMIS: Patient-Reported Outcomes Measurement Information System
SMART goals: Specific, Measurable, Achievable, Realistic, Timed goals

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Original Paper

Acceptability, Usability, and Views on Deployment of Peek, a Mobile Phone mHealth Intervention for Eye Care in Kenya: Qualitative Study

Vaishali Lodhia[1], MBBS, MSc.; Sarah Karanja[2], MA; Shelley Lees[3], PhD, MRes; Andrew Bastawrous[4], MRCOphth

[1]London School of Hygiene and Tropical Medicine, London, United Kingdom

[2]AMREF, Nairobi, Kenya

[3]London School of Hygiene and Tropical Medicine, Department of Global Health and Development, London, United Kingdom

[4]London School of Hygiene and Tropical Medicine, Clinical Research Department, International Centre for Eye Health, London, United Kingdom

Corresponding Author:
Vaishali Lodhia, MBBS, MSc.
London School of Hygiene and Tropical Medicine
Keppel Street
London, WC1E 7HT
United Kingdom
Phone: 44 7796277602
Fax: 44 20 7436 5389
Email: vaishali.lodhia@gmail.com

Abstract

Background: The Portable Eye Examination Kit (Peek) is a mobile phone–based ophthalmic testing system that has been developed to perform comprehensive eye examinations. Shortages in ophthalmic personnel, the high cost, and the difficulty in transporting equipment have made it challenging to offer services, particularly in rural areas. Peek offers a solution for overcoming barriers of limited access to traditional ophthalmic testing methods and has been pilot tested on adults in Nakuru, Kenya, and compared with traditional eye examination tools.

Objective: This qualitative study evaluated the acceptability and usability of Peek in addition to perceptions regarding its adoption and nationwide deployment.

Methods: Semistructured interviews were conducted with patients and analyzed using a framework approach. This included analysis of interviews from 20 patients, 8 health care providers (HCPs), and 4 key decision makers in ophthalmic health care provision in Kenya. The participants were purposefully sampled. The coding structure involved predefined themes for assessing the following: (1) the context, that is, environment, user, task, and technology; (2) patient acceptability, that is, patients' perceived benefits, patient preference, and patient satisfaction; (3) usability, that is, efficiency, effectiveness, learnability, and flexibility and operability of Peek; and (4) the benefits of Peek in strengthening eye care provision, that is, capabilities enhancer, opportunity creator, social enabler, and knowledge generator. Emerging themes relating to the objectives were explored from the data using thematic analysis.

Results: Patients found Peek to be acceptable because of its benefits in overcoming the barriers to accessing ophthalmic services. Most thought it to be fast, convenient, and able to reach a large population. All patients expressed being satisfied with Peek. The HCPs perceived it to satisfy the criteria for usability and found Peek to be acceptable based on the technology acceptance model. Peek was also found to have features required for strengthening ophthalmic delivery by aiding detection and diagnosis, provision of decision support, improving communication between provider and patient and among providers, linking patients to services, monitoring, and assisting in education and training. Some of the deployment-related issues included the need for government and community involvement, communication and awareness creation, data protection, infrastructure development including capacity creation, and training and maintenance support.

Conclusions: According to all parties interviewed, Peek is an acceptable solution, as it provides a beneficial service, supports patients' needs, and fulfills HCPs' roles, overall contributing to strengthening eye health.

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KEYWORDS

mobile phone; mHealth; qualitative; ophthalmic testing; acceptability; usability; Kenya

Introduction

Background

The estimated number of visually impaired people worldwide is 285 million, of which 39 million are blind [1]. Up to 80% of global visual impairment is preventable [1].The burden is unequally distributed, with the largest proportion living in low-income nations of Africa and Asia [2]. Loss of sight is associated with considerable emotional, social, and economic consequences, especially among the poor [3,4]. One of the biggest challenges to reducing the burden of visual impairment is the significant shortage of ophthalmic health care [5]. Ophthalmic testing equipment is often expensive, bulky, and immobile, making it difficult to deploy an ophthalmic service in rural areas, particularly where there are fewer ophthalmic professionals.

Tackling avoidable vision loss requires strengthening of health systems (HSs) in order to achieve universal access to ophthalmic services. This has been a major focus of the global ophthalmic public health community and a key goal of the recent World Health Organization (WHO) global action to improve eye health for everyone over the next 5 years, building on the principles of VISION 2020 [6].

Mobile health (mHealth) refers to the use of mobile technology, such as mobile phones (MPs), to provide health services. Mobile health is a growing field and its potential in improving health and health care delivery has been well demonstrated [7-9]. There are significant opportunities to leverage the benefits of mHealth in expanding health care delivery with the increasing uptake of MPs in the developing world [10]. Furthermore, the scope of mHealth has increased in recent years with the introduction of smartphones, which offer enhanced functionality and user interfaces over traditional multimedia devices.

In Africa, smartphones are becoming more affordable, driven by greater competition among operators and manufacturers. Smartphone subscriptions in Africa have been forecast to increase from 79 million to 412 million between 2012 and 2018 [11]. Nevertheless, the evidence base for smartphone use in health care is lacking, particularly contextual, process and health outcome evaluations in low- and middle-income countries [12-16].

This study aimed to evaluate a smartphone-based ophthalmic examination system with clip-on hardware, the Portable Eye Examination Kit (Peek), which has been developed and introduced as a user-friendly and affordable alternative to perform comprehensive ophthalmic examinations. Figures 1 and 2 show how Peek is being used to take a fundal image and to examine a cataract. Peek offers a potential solution to overcoming barriers of traditional ophthalmic testing methods and thereby contributes to the VISION 2020 goals [17].

Objectives

This qualitative study was carried out to assess patients', health care providers' (HCPs'), and stakeholders' (decision makers in ophthalmic service provision are referred to as “stakeholders”) perspectives on the adoption of Peek for improving the provision of ophthalmic services in Kenya. This included a formative evaluation of the acceptability and usability of Peek compared with traditional methods of ophthalmic testing. In addition, its potential for strengthening ophthalmic services and potential barriers and facilitators to adoption and deployment of the technology were explored.

Figure 1. Retinal imaging by Peek.

Figure 2. Peek for cataract testing outside patients home.

Methods

This study was undertaken within the follow-up phase of the Nakuru Eye Disease Cohort Study in central Kenya, a population-based study, which recruited 5000 individuals from 100 clusters [18].

The sampling strategy for this qualitative study involved purposeful sampling, and the patient sample was chosen from the 100 clusters based on varying sex, age, geographical location, educational levels, and income. The purpose was to maximize diversity and capture common themes relating to the intervention across a range of participants with differing characteristics [19]. Nakuru district was chosen because it offers a diverse population in terms of ethnicity and economic activities [18].

The qualitative study consisted of semistructured interviews with all HCPs (ie, 8) recruited for testing Peek, patients (ie, 40) examined with Peek, and key stakeholders (ie, 4) involved in shaping ophthalmic provision in Kenya and were chosen from the ministry of health, an ophthalmic teaching hospital, and selected nongovernmental organizations (NGOs). All patients underwent visual acuity (VA) testing using Peek at their homes, whereas fundal images were taken at a temporary clinic in that cluster. At this clinic, they also underwent repeat VA and funduscopic examinations using traditional equipment.

Four interviewers were trained to conduct the interviews and were provided semistructured interview guides. All interviews were audio recorded with the consent of all participants. The patient interviews were conducted in Kiswahili and then transcribed and translated. Conversely, the HCP and stakeholder interviews were conducted in English.

The Nakuru Eye Disease Cohort Study was approved by the African Medical and Research Foundation ethics board, which included pilot testing of Peek and conducting interviews as part of the larger project. Full written consent was obtained from all parties including the patients, HCPs, and stakeholders before each interview and was available in Kiswahili and English.

The interview transcripts were analyzed using NVivo version 10 [20]. A framework analysis approach was used, creating predefined themes for the coding structure. The coding framework was guided by theoretical constructs from literature on mobile usability, acceptability of technology, and previous mHealth reviews and literature on assessing benefits of mHealth in strengthening health care delivery [21-34].

To assess the acceptability and usability of Peek, it was deemed important to first understand the context within which it is to be implemented [21-23]. The analysis of the context was therefore carried out through a coding framework proposed by a qualitative review of mobile usability studies, which took into account the environment, user, task, and technology [21]. The themes involved assessing patients' and HCPs' perceptions of (1) ophthalmic service provision; (2) the barriers to seeking and accessing ophthalmic services, that is, environment; (3) HCP role and experience, that is, user; (4) understanding the purpose of Peek, that is, task; and (5) familiarity and views regarding mobile technology.

The coding for assessing patient acceptability of the Peek testing process and its functionality was informed by the definition of acceptability by Ayala and Elder (2011) [24]. They proposed that acceptability refers to determining how well an intervention will be received by the target population and the extent to which the new intervention or its components meet the needs of the target population and organizational setting. The themes included assessing (1) patients' perceived benefits of Peek, (2) patient satisfaction, and (3) patient preference.

The International Organization for Standardization defines usability as the extent to which a product can be used by specific users to achieve specific goals with efficiency, effectiveness, and satisfaction in a specified context of use [25]. A number of usability dimensions have been proposed by Coursaris and Kim (2006) in their qualitative review of mobile usability studies, which informed the coding framework for assessing usability of Peek by HCPs [21]. The themes included (1) efficiency, (2) effectiveness, (3) learnability, and (4) flexibility and operability.

The Technology Acceptance Model (TAM) and its extension, TAM2, were used as a guide to assess user acceptability of the technology [26-29]. This proposes that acceptability or prediction of use of a technology depends on the attitude toward it, which is a function of ease of use and perceived usefulness. The analysis of perceived usefulness was informed by assessing HCPs' perceptions of the benefits. Several studies to date have looked at the benefits of mHealth, and several frameworks have been proposed for assessing benefits in strengthening health care provision [30]. This analysis has therefore adapted a model based on a combination of four frameworks to appraise the potential benefits of Peek in strengthening eye care delivery. The four main themes of the framework were adapted from the Information Communication Technology for Healthcare Development Model [31]. These are capabilities enhancer, social enabler, opportunity producer, and knowledge generator. The subthemes were based on three other frameworks proposed for guiding assessment of mHealth in strengthening HSs [9,30,32,33]. The components chosen for the framework are also in line with the categories of mHealth initiatives established by the WHO [34].

A thematic analysis was also conducted to explore emerging themes and subthemes related to the study objectives that were inferred from the data [35-37]. Analysis was conducted until saturation was reached, which was 20 patient interviews, all 8 HCP interviews, and all 4 stakeholder interviews. After this, the coding was summarized and modified, and connections were made between related themes and between the 3 groups of interview participants.

Results

A summary of all the themes discussed in this section is given in Textbox 1.

Textbox 1. Results section summary.

Contextual factors

- Environment
  - Patient demographics
  - Barriers to seeking and accessing services
    - Cost
    - Lack of ophthalmic facilities, qualified providers, and support
    - Time
    - Lack of awareness
- User
  - Role and experience of health care providers
- Task
  - Patient's and health care provider's understanding of Portable Eye Examination Kit
- Technology
  - Attitudes toward mobile phones

Patient acceptability

- Perceived benefits of Portable Eye Examination Kit
- Patient preference
- Patient satisfaction

Usability dimensions

- Efficiency
  - Time
  - Multitasking
  - Portability and convenience
  - Cost
- Effectiveness
- Learnability
- Flexibility and operability

Benefits

- Capabilities enhancer
  - Detection and diagnosis
  - Provider performance
  - Decision support
- Social enabler
  - Provider-to-patient communication
  - Provider-to-provider communication
- Opportunity producer
  - Linkage of patients to ophthalmic provision
  - Monitoring and surveillance

- Knowledge generator
  - Training and education

Contextual Factors

Patient Demographics

The number of males and females was equal and the ages of the patients ranged from 50 to 77 years. The educational levels varied from no education to primary, secondary, and tertiary education and were evenly represented in the sample of patients. With regard to occupation, 11 patients were farmers, 2 teachers, 2 businessmen or businesswomen, an engineer, an industrial chemist, a civil servant, and a secretary. Apart from one businessman who reported an annual income of 4,000,000 Kenyan shillings (KES), incomes varied mainly from 1000 to 50,000 KES per month with an average of 16,000 KES.

Environment (Patients' and HCPs' Perceptions of Current Eye Service Provision and Perceived Barriers to Seeking and Accessing Eye Services)

Cost

Six of the HCPs and almost all patients stated seeking ophthalmic services as unaffordable when referring to having to pay for hospital bills and transport.

> *...seeking eye treatment is quite expensive. Then again, I was not in a position to seek treatment. As farmers, we have low standards of living and therefore cannot afford to seek regular eye healthcare. We only go to hospitals when eye problems persist.* [Patient #23, male]

Lack of Ophthalmic Facilities, Qualified Personnel, and Support

The general opinion among the HCPs was that the availability of eye services in Kenya was inconsistent, with poorer provision in rural areas. The majority mentioned that patients had to travel long distances to access eye care, which was made more difficult because of poor infrastructure and roads. Another issue raised was scarcity of qualified ophthalmic personnel. Many described existing services as being overburdened as a result. With regard to prevention, most HCPs reported that they were not aware of any formal preventive measures put in place by the government in the region studied. The majority mentioned often taking the initiative to educate patients when seeing them.

Similarly, from patients' point of view, the government services in rural areas were reported to be limited to dispensaries with no specialist ophthalmic testing services, which only provide eye medications at a cost. Most patients also mentioned being on their own with little support posing a challenge for them to access treatment either because of the inability to access transport or due to having to prioritize other issues to sustain their livelihood. All those living in remote settings stated they were constrained from accessing more specialist services because of long distances.

In contrast, those living in Nakuru, an urban town, felt that ophthalmic facilities were generally accessible via government hospitals, private hospitals, opticians, and missionary hospitals.

> *Most patients are very far from health facilities, we have poor infrastructure and most clinics, health facilities that are near people don't have eye clinic specialist, they just have a general doctor or clinician and that is all. So you find that most patients don't get specific eye treatment.* [HCP #6, female]

> *It is far and then again, it is not easy to find. It is hard because even fare has to be considered and on top of that, there is the fee for treatment which is steep.* [Patient #2, female]

Time

Time was reported as a significant barrier to accessing eye services by 4 HCPs. Patients also had a similar opinion, especially those living in urban settings where long queues at government facilities were reported as a major obstacle because of difficulty taking time off work and potential loss of income.

> *Transportation and also long queues, time is also a factor because some are trying to work hard to see how the family could get along so they say the issue of the eye can be put aside, although he cannot see properly he says it's an issue he can attend to later.* [Patient #39, male]

Lack of Awareness

Six HCPs mentioned lack of knowledge of eye conditions and lack of awareness of the importance of early detection and treatment as a barrier to patients seeking health care in both rural and urban settings. However, they perceived this to be more of a problem in rural areas due to lower educational levels and less exposure to health care in general.

Patients acknowledged that they had limited knowledge of eye problems. Most patients gave similar explanations for causes of eye problems and demonstrated a particularly limited understanding of chronic conditions. The most frequently mentioned causes, as perceived by patients, were poor hygiene, dust, smoke from cooking, direct sunlight, and unbalanced diet. A couple of participants mentioned "jerreri" as a cause, which means cataracts in their local language. Few patients mentioned other causes such as inherited diseases, work, alcohol, and smoking.

Interestingly, most patients revealed that they did not see the importance of regular eye checks despite being affected by changes in their vision. Only 4 patients brought up the importance of timely eye checkups as a means of preventing visual deterioration.

When asked about delays in seeking treatment, the most common reason given by patients and HCPs was that eye problems were not perceived to be serious enough to require

urgent treatment, particularly when faced with barriers to accessing services. Furthermore, patients and HCPs perceived local myths and traditional practices in their communities to be a consequence of poor knowledge, leading to patients not seeking or accepting treatment. They highlighted the need for awareness creation through education and involvement of village chiefs.

> *...I thought that the problem was not very serious and I waited to see whether I would get better on my own but when that did not work, I sought medical treatment. This is because there are no mobile eye doctors like you doing rounds creating awareness on eye issues. Someone like I will wait until I am sick to seek treatment because there is no one giving people information to help prevent these problems.* [Patient #9, male]

> *They should receive help from people like chiefs who are more knowledgeable. They should be helped in accessing treatment. It can help in prevention. Because most people are now useless.* [Patient #2, female]

User (Role and Experience of Health Care Providers)

There were 6 male and 2 female HCPs consisting of ophthalmologists, ophthalmic clinical officers, and members of the advance team. The members of the "advance team" were responsible for tracking participants for the study enumeration, using Peek to test vision at patients' home and ophthalmic testing using traditional equipment in clinics. One of them had the additional responsibility of software maintenance. An ophthalmic nurse was also part of this team and was also involved in counseling and preparing patients for surgery. Most HCPs had no prior training in eye care before joining the Nakuru Eye Disease Cohort Study. Their experience in ophthalmic service provision was therefore mainly limited to the year during which the study took place, with the exception of the ophthalmologists, one of whom had 18 months and the other 4 years of experience.

Task (Understanding of Peek)

When asked to describe Peek and the examination process, the responses from HCPs varied based on their role and experience as ophthalmic providers. Most HCPs correctly mentioned that Peek incorporates several examinations in one device, thus enabling a basic eye examination comparable to traditional techniques. All the HCPs who were primarily responsible for providing outreach services described Peek as a tool for VA testing, and most needed prompting before mentioning its other uses in performing eye examinations such as anterior eye examination and fundoscopy. Most HCPs also highlighted Peek's capability for data analysis, information sharing, communication with colleagues, and other basic functionalities such as browsing, testing, and calling.

The patients interviewed demonstrated a good understanding of the technology and its purpose for ophthalmic testing and described it as an alternative and possible substitute for traditional eye examination. Two patients, however, were not aware that the MP was being used for eye examinations.

Technology (Attitudes Toward Mobile Phone Technology)

Patients, HCPs, and stakeholders all had positive attitudes toward MPs and smartphone technology. Mobile phones were referred to as innovative, advanced, new, and highly technological. They reported that the technology had made communication easier. Several patients revealed a familiarity in using MPs and felt that the attitude of the community toward MPs depends on exposure, awareness, and education. The HCPs and stakeholders had similar views and mentioned that MP use was widespread in the area. One HCP and patient reported that the use of MPs in Kenya was best known by the money transfer initiative called M-Pesa that has been adopted by a large proportion of the population. All participants were optimistic about the potential uses of MPs, especially smartphones, and portrayed enthusiasm for technology.

> *I think that the MP is a highly technological piece of equipment. It is very advanced.* [Patient #27, female]

> *In Kenya generally people are used to SMS, they are used to M-Pesa and the technology which is there is almost comparable to that. I think the kit generally most people are able to operate.* [HCP #3, male]

> *We all like new technology, we are all thirsty for new innovations in eye health because of the many challenges in service delivery.* [Stakeholder #4]

Patient Acceptability

Benefits as Perceived by Patients

All patients perceived Peek to be beneficial as its portability brings examination and treatment closer to them. They perceived it as a way of overcoming many of the aforementioned barriers. The patients also suggested that it could increase detection of eye problems because it can reach a larger population. This could be achieved by providing earlier eye examinations for those who lack awareness or those unable to access existing eye services. The use of Peek was also seen to have the potential to increase awareness about eye conditions in general as it uses mobile technology, which is considered to be acceptable for patients. Many patients also deemed Peek to be efficient and economical for themselves and the HS because it saves time, costs less, and reduces the burden on health care personnel. When patients were asked about how long it took to receive an eye examination with Peek, 17 of the 20 patients recalled the time to be between 2 and 20 minutes. The other 3 patients did not mention an exact time. When they were asked about the duration of traditional eye examinations, the responses varied between 30 minutes and 4 hours.

Patient Satisfaction

All patients stated that they were satisfied with the service offered. Eighteen of 20 patients did not report concerns regarding the technology. Moreover, when asked about further comments about Peek at the end of the interview, the majority of patients stated that they were hoping for the service to be more accessible to them.

Nevertheless, some patients expressed potential doubts about their community's uptake of Peek. These will be discussed later in this paper.

Patient Preference

When asked about whether patients preferred traditional examinations or Peek, 10 patients expressed a preference for Peek, 7 stated no preference, and 3 preferred the traditional examination. The main reasons for preferring Peek were shorter examination time, simplicity, efficiency due to multiple examinations combined in one tool, being seen at home, and the increased potential coverage of the population in need. Those who did not express a preference stated that their decision would be dependent on the actual availability of the intervention. Two patients who preferred traditional examinations referred to the ease of reading larger letters. Another patient described clinic equipment as having fewer potential side effects, although he then conveyed his support for Peek to be incorporated into policy service provision in rural areas where the need was perceived to be greatest.

Patient Acceptability as Perceived by Health Care Providers

The HCPs also perceived Peek to be acceptable to patients. They reported that patients appreciate a service that is brought closer. Furthermore, according to HCPs patients were curious, interested, and willing to be examined by the new technology. Some HCPs also mentioned that the use of Peek helped overcome patients' fears related to being tested with traditional techniques, as mobiles are more familiar and therefore patients are likely to be more comfortable being tested with MPs.

> *The application being the first to debut in Kenya mostly using testing people with it, it is amazing and people are like they wish to be checked using the phone.* [HCP #4, male]

Analysis of Health Care Providers' Usability of Peek

Usability Dimensions

Bearing in mind the context of use described earlier, an analysis of usability was carried out using the predefined usability dimensions, that is, efficiency, effectiveness, learnability, and flexibility and operability, as summarized in Table 1. While assessing efficiency, the following subthemes became apparent: speed, multitasking, convenience, and cost. Table 1 summarizes the analysis of perceptions of the HCPs regarding usability of Peek as per predefined usability dimensions.

Table 1. Usability dimensions.

Usability dimension		No. of HCPs[a]	Rationale given by HCPs	Benefits relating to usability dimension	HCP quotes
Efficiency					
	Time	8	Simple and easy to use, with less manual record keeping.	Ability to see more patients, early diagnosis, and treatment.	*" ...it will be more effective in that we will be able to get to see more patients with eye problems and in that case I will be able to solve them early enough and our patients will not have to go blind..."*
	Multitasking	6	Requires less equipment to navigate and manpower to conduct examinations.	Saves human resources.	*" ...you can multi task it by doing all the examination at the same place without moving just by the touch of the application, so it will make it better."*
	Portability and convenience	7	Easier to carry around compared with traditional equipment.	Increase access and coverage in remote areas.	*" ...it's portable and one can be able to access rural areas where infrastructure is poor so in terms of accessing those places you will be able to get people who could not think of getting help..."*
	Cost	6	Cheaper equipment (10,000-40,000 KES[a] compared with more than 1,000,000 KES for traditional equipment), transport, and negligible software costs and replacement costs.	Economic gains for patients and service provisions.	*" ...the cost of one Portable eye kit does like very many examination procedures compared to the machines so it makes it cheaper, two the cost of transport is cut down because I'll be able to visit the client at his/her own convenience..."*
Effectiveness		6	Accurate, equal, or better than traditional equipment.	Ability to provide better analysis of findings, compared with the substitute.	*" The phone is automatically accurate than the traditional type of equipment. PEEK is more advanced than the traditional equipment gives you the exact figures and images. It is very accurate. Excellent in fact"*
Learnability		8	Clear instructions; though useful, no expertise required.	Usable by less qualified HCPs with limited smartphone knowledge.	*" ...anybody as long as you have something in between your ears that is a brain then you can actually work. Because everything is just written and where it is not written you can actually see it everything is self-explanatory with algorithms."*
Flexibility and operability		8	Quickly modifiable based on user feedback and robust technology.	User-friendly, easy to maintain, and meets different needs.	*" ...it is still open ended it is not closed so it is it is able to accommodate, new things and new ideas and new situations that may vary from one region to another from one country to another so it is adaptable."*

[a]HCP: health care provider; KES: Kenyan shilling.

HCPs' and Stakeholders' Perceptions of Benefits of Peek in Eye Care Delivery Using a HSs Approach

Capabilities Enhancer

Detection and Diagnosis

The HCPs and stakeholders believed that Peek can increase the chances of diagnosing eye problems and is thought to have the potential to be used as a screening tool to increase detection of poor vision. They perceived earlier detection to be beneficial in reducing the burden of blinding eye disease and thereby increasing general standards of living. Nevertheless, stakeholders stated that the success of Peek as a screening tool will depend on proven accuracy, sensitivity, availability, and ensuring high-quality service delivery.

> *Well the more sensitize a technology you have for detecting problems and the more easily available it is, it means you are going to start detecting many more patients and so that's good for the patients so that more people get to know more earlier that they have a problem.* [Stakeholder #1]

Provider Performance and Decision Support

The opinion among HCPs and stakeholders was that Peek could allow for task shifting and improved human resource management by providing support to community health volunteers (CHVs). This was seen as a potential solution to fill in for the shortage of ophthalmic workforce. Peek was perceived to lead to improved outcomes of the services provided as a direct result from its user-friendly platform, inbuilt decision-support algorithms, and data analysis capabilities. These features of the application were also perceived to help in managing and organizing workload of HCPs, for example, by prioritizing referrals. Furthermore, the application was thought to have an

impact on increasing HCP motivation and self-confidence in detecting and consequently managing eye problems.

> *I can even be able to collect, gather data from the field and it gives me some clear information on some decisions that I am about to make. The same way the smartphone and for example PEEK is doing; it is able to do some basic examination that is able to separate those who need to see a doctor urgently and those who do not need urgently.* [Stakeholder #3]

Social Enabler

Provider-to-Patient Communication or Client Education

Most stakeholders stated the value of Peek in providing instant feedback to patients through the images, which are immediately available on the phone. Stakeholders described its value in terms of explaining the diagnosis to the patient, reinforcing patient understanding, decision-making, and confidence. According to one stakeholder, this is further enhanced by the ability to contact relatives who are unable to make it to the clinic. Stakeholders highlighted that seeing an image of a damaged retina and optic nerve can help patients understand the seriousness of their problem and thus they will be more likely to urgently seek and comply with treatment as a result.

Provider-to-Provider Communication

Stakeholders referred to the potential role of Peek in enhancing communication between HCPs as a beneficial feature, for example, enabling remotely located ophthalmologists to provide less qualified HCPs with support in decision-making. Peek was also perceived to overcome current problems in data transfer by generating images in a format that can easily be transferred to other HCPs, which existing equipment does not allow. These qualities of Peek are further reported as vital for task shifting to be successful.

Opportunity Producer

Linkage of Patients to Ophthalmic Provision

Similar to HCP views, according to all the stakeholders interviewed, Peek was perceived as bringing service provision closer to patients who need it most. This was deemed possible by being able to conveniently and efficiently provide ophthalmic services in remote settings, thereby overcoming logistical issues in having to set up clinics. Additionally, 2 stakeholders commented on the ability of Peek to increase public confidence in ophthalmic workers and in service provision, which is currently challenged by poor uptake of eye services.

> *...those who are in the most remote areas who have the highest prevalence for blindness will now be linked to the health system and so people will be able to find them and treat them.* [HCP #7, male]

Monitoring and Surveillance

Features of Peek such as data storage and Global Positioning System tracking are thought to be desirable by stakeholders in strengthening monitoring and surveillance, thereby better contributing to policy-making and resource planning. Additionally, they perceive Peek to enhance follow-up by being able to locate patients easily.

Knowledge Generator

Training and Education

Peek was also deemed as a training opportunity by both HCPs and stakeholders, because discussing management of eye problems with qualified and experienced ophthalmic professionals is thought to increase knowledge and skills of those with limited training. Furthermore, according to stakeholders and HCPs, Peek offers an opportunity to educate and sensitize the population about eye health. Consequently, the overall opinion was that Peek contributes to increased patient awareness and knowledge.

Analysis of Perceived Barriers, and Proposed Facilitators for Overcoming Potential Barriers to Adoption and Deployment

Neither the patients nor the HCPs reported any major obstacles with the use of Peek during the examination. However, the following themes emerged from all parties as potential system-related challenges in implementation that need to be considered for deployment.

Government Involvement

Lack of integration with the national health system and potential lack of government involvement were seen as major challenges to deploying Peek. Early involvement of government, policy makers, and health management teams in decision-making was therefore considered by stakeholders and HCPs to be essential to ensure sustainability of the program. These participants proposed working with the government at all stages from development to implementation. State involvement was also regarded as essential to gain public trust in the intervention; integrate services; and setting guidelines, standards, and protocols for national implementation and adoption.

Funding

Lack of funding was discussed as a barrier to deployment and sustainability of the program. Government support and partnership with NGOs was put forward as a solution to increase availability and affordability of Peek and integration with existing services. The new health restructuring in Kenya, where management has been devolved to county level, was perceived to be most likely beneficial in sustaining the intervention as resources are more likely to be spent where most needed. However, the priority given to eye health nationally was seen by the stakeholders to influence any future decisions about funding. Moreover, as indicated by one stakeholder, a cost-benefit analysis and evidence for effectiveness are essential for obtaining funding.

Other options suggested for funding were donor support for financing and other resources required for the program. Stakeholders also suggested that the government would financially benefit from adopting Peek, as it is perceived to be cost-effective compared with traditional ophthalmic testing methods.

> *From an economist point of view, I would say it is a good, it is a project worth financing.* [Stakeholder #3]

Communication and Technology Awareness

Although none of the patients expressed any reservations or fear of being examined by Peek, some mentioned that there is a possibility that certain people may not understand the purpose and value of the application. Another perceived barrier to adoption of using Peek was miscommunication. For instance, initially 1 patient reported having reservations about the use of Peek but was comfortable with it as soon as the examination steps were clearly explained. Furthermore, acceptance was also deemed to be governed by the level of education. Therefore, the importance of familiarity with MPs and the need for good communication on the utility of Peek were highlighted by several patients, HCPs, and stakeholders. Some examples were given for reasons of possible misunderstanding in the community, such as the phone being used to take patient's pictures instead of retinal images, cultural reservations about MPs, and fear of MPs having negative health effects.

> *Counselling and sharing with them and giving them reason as to why, especially if the patient needs examination, you just understand the patient and help the patient to understand.* [HCP #6, female]

Training and Product Support

A potential challenge mentioned by both stakeholders and HCPs is the need for setting up training for using Peek and product support if it were to be deployed sustainably. Consequently, they suggested the need to plan for a strong support team. Nevertheless, Peek was perceived as more sustainable than traditional equipment, with less likelihood of requiring replacement of expensive components. From patients' point of view, equipment quality was an important factor to ensure a high standard of care provision.

> *...it is more sustainable than the equipment we are providing and that is what I see. Because if these equipment breakdown, they have to be serviced and they have to buy spare parts, of which right now we have several equipment that are not working because of spare parts.* [Stakeholder #4]

Data Protection

According to HCPs and stakeholders, maintaining confidentiality of patient information is paramount and a potential barrier to sustainability and acceptability of the intervention. They proposed the need to ensure that a robust and secure data encryption system is in place. In addition, good communication was also reported as necessary to ensure that patients understand and are reassured about confidentiality. One stakeholder involved in building a central ophthalmic data collection unit, the Ophthalmic Service Unit designed to be linked to Hospital Management Information Systems, stated that it has been difficult to implement the system in Kenya. The suggestion for the implementation process was that it is important to link patient data, collected using Peek, to the HCPs' clinic as well as the central database for safekeeping.

Another issue raised was that mobile phone devices could be stolen when used in insecure remote areas, therefore reinforcing the need for robust security measures in addition to a data protection system.

Community Involvement

Stakeholders and HCPs described the benefits of training the local population for community mobilization. They suggested that training the local population to run the program will overcome any potential obstacles related to acceptability and sustainability. Patients saw the importance of community participation as key to building trust and confidence in the program and put the population at ease. From one stakeholder's point of view, getting public support is also very important to tackle cultural barriers. One patient referred to the M-Pesa service as an example of a program that has managed to drive community mobilization.

> *...early involvement and train locally available people to actually address some of those bugs that can arise that can cause a problem...* [HCP #3, male]

Increase in Demand for Ophthalmic Treatments

One obstacle mentioned was that the HS may not be able to cope with managing the increase in cases detected by Peek. A solution suggested by both HCPs and stakeholders to combat this problem is recruiting CHVs. The value of Peek in supporting HCPs who have limited training in eye care playing the role of CHVs has been highlighted throughout this study. Moreover, a stakeholder mentioned how Peek can be used to prioritize cases, which helps with shifting demand and coping with increasing workload. One stakeholder also proposed to introduce Peek to those trainees in the community who will become future HCPs.

Infrastructure

The accessibility of MPs and infrastructure supporting the use of mobiles was reported as being key for sustainability of Peek by HCPs and stakeholders. Infrastructure-related barriers raised were shortage of devices and poor mobile network provision and internet coverage, making it difficult to send across images and patient information to the central database as well as other HCPs for advice. They proposed partnering with and acquiring support from key network providers to increase availability and affordability of both the device and mobile data usage. Power shortages in rural areas leading to inability to charge phones were also mentioned as potential barriers to service delivery with Peek. Provision of HCPs with a battery-powered charging system and backing up data were given as potential solutions.

> *You know the challenges of network in Kenya, the downs, you know sometimes it just disappears in some areas and especially in the villages, in the remote areas.* [Stakeholder #2]

Discussion

This qualitative study offers a comprehensive understanding of the potential value and barriers to the deployment of the smartphone-based eye examination system, Peek, in developing countries with limited coverage of ophthalmic services. Peek as a stand-alone system is useful; however, in conjunction with smartphone functionalities it offers a highly desirable advantage.

To date, studies evaluating mHealth have mainly assessed basic use of MP technology with limited evidence on the value of using smartphones for health care [7,12]. This study showed that Peek is an acceptable examination kit for HCPs, patients, and stakeholders and has the potential to strengthen the delivery of eye care in resource-poor contexts. The study has also illustrated the potential challenges and facilitators that are likely to affect the adoption and deployment of Peek.

The analysis of the user, task, technology, and environment gives an overall understanding of the context in which Peek is being evaluated. The patient diversity, patient demographics, and the HCP roles and experience utilized in this study are considered to be the representative environment for which Peek has been designed and in which it will likely be deployed. Most HCPs had limited ophthalmic specialist training, serving as CHVs with experience restricted to the year in which the Peek study was undertaken. This has provided useful insights, because if Peek were to be deployed, it is likely that CHVs will be recruited because of the shortage of ophthalmic professionals in developing countries.

Overall, HCPs demonstrated a good understanding of the utility of Peek, that is, its task. The analysis of attitudes toward technology revealed that HCPs, patients, and stakeholders perceived the population as being familiar with MPs and receptive to them being used. These views reflect the increasing penetration of MPs and more specifically smartphones in Kenya. This enthusiasm for MPs has been greatly influenced by a number of initiatives: M-Pesa's money transfer initiative that has driven MP usage in the remotest of settings and Safaricom's initiative to make smartphones more affordable through the introduction of cheaper android devices, which have led to increasing smartphone subscriptions [11].

The analysis of the context also revealed significant barriers to seeking and accessing ophthalmic services in the current HS. Both HCPs and patients felt that there was a rural–urban disparity with almost no established services in rural settings. This was reported to lead to patients having to travel long distances, having to encounter long waiting times at overburdened government facilities, and having a lack of awareness about timely detection and treatment.

Peek was found to be acceptable to patients, all of whom expressed being satisfied with Peek. Moreover, the analysis revealed that contentment with the service was often related to the quality of service provision. Most participants supported the use of Peek because it was perceived to be fast and convenient and to be able to reach a larger population in need, in addition to overcoming the aforementioned barriers. Peek is also deemed to have generated a lot of interest among the communities and is therefore an opportunity for increasing awareness of eye health within the population. Although limited, a handful of studies have shown the value of mHealth initiatives in creating awareness, for instance, in general health, HIV/AIDS, and women's health in low-income countries [34].

The analysis of the usability of Peek based on predefined usability dimensions demonstrated that per HCPs' perceptions, Peek generally fulfills the criteria for all dimensions assessed. These included efficiency, effectiveness, learnability, and operability and flexibility. In addition to the usability of Peek, the analysis confirms that Peek is acceptable to HCPs. This was demonstrated by their perceived ability to use Peek easily, fulfill their role, and meet the challenges of ophthalmic provision.

An analysis of the views of HCPs and stakeholders using a model adapted from relevant literature showed the value of Peek in strengthening the HS's ability to provide eye services [30-33]. Peek was perceived to be a capabilities enhancer for HCPs through the provision of diagnostic and decision support. This has already been introduced as an important feature of mHealth initiatives in supporting HSs as proposed in current literature [9,33]. The possibility of using Peek as a screening tool is also discussed under this theme, and its success is thought to be dependent on being able to prove its accuracy, sensitivity, accessibility, and ability to offer a high standard of service delivery. It is therefore vital that these qualities are satisfied in addition to other criteria required for enrolling a screening service before Peek can be rolled out for this purpose [38]. A qualitative study of the accuracy of the tool has been carried out alongside this qualitative study, which has proven its accuracy, repeatability, and consistency as a vision-testing tool. Another study is also underway to determine its suitability as a screening tool in children at school.

Peek's value in creating opportunities that help in supporting health care delivery was also highlighted. These included offering eye care closer to patients and enabling monitoring and surveillance. Additionally, Peek was deemed to be a social enabler and improved communication between providers themselves as well as with their patients. Another theme highlighted was knowledge creation and development of skills by offering training opportunities. The outlined benefits of Peek show its potential value in supporting CHVs in providing a high standard of care through its inbuilt functions, because these support decision making as well as communicating with qualified ophthalmic professionals who can offer advice remotely. Other studies of mHealth in developing countries have demonstrated the value of MPs in tackling the current barriers to service provision and improving the range and quality of services offered by CHVs [34,39,40]. Moreover, these benefits are likely to play an important role in the near future, with the increasing double burden of disease in Africa where chronic ophthalmic conditions, such as glaucoma, age-related macular degeneration, and diabetic retinopathy, are also likely to become more prevalent. As a consequence, the need for Peek to be offered within a well-coordinated HS that is capable of screening for and managing these conditions as part of secondary prevention efforts is likely to become increasingly essential.

Given the paucity of studies and established guidelines on large-scale implementation of mHealth, the views of all parties gathered during this qualitative analysis assisted in understanding the challenges and facilitators in deploying Peek.

This analysis brought out several common themes that highlight key considerations that are likely to affect adoption of Peek. Many of the challenges reported are similar to those mentioned in previous mHealth studies [41]; however, several unique considerations were also revealed that are specific to Peek and the context in which it is likely to be implemented. The themes

that emerged included the need for (1) government support and involvement in deployment, (2) building capacity to train HCPs and maintenance of Peek, (3) maintaining a high standard of care and good communication about the purpose of using Peek with all patients, (4) community mobilization, (5) increasing capacity to manage increasing demand for eye treatments, (6) ensuring general eye health awareness and linking with primary health care, (7) ensuring data protection, (8) ensuring accessibility to smartphone technology at low cost, and (9) infrastructural support such as mobile charging systems and improved network coverage. These considerations serve as guidance for the future implementation of Peek.

Although previous mHealth studies have been conducted on a small scale, a review of literature has shown that there is a clear opportunity for successful mHealth interventions when proven to be acceptable, accessible, easy to use, affordable, appropriate to the local context, and integrated within the HS [8,39,42-46]. Peek therefore shows promise for success.

Limitations

Since the qualitative analysis was carried out on data that had been collected retrospectively, there was limited opportunity for an iterative process whereby initial data analysis can guide further interviews. Moreover, in an attempt to answer specific predefined objectives, data were collected from semistructured interviews, which limited open-ended questions. Additional open-ended questions would have allowed for a more in-depth exploration of themes.

Conclusion

The analysis of context illustrated the perceived importance of addressing rural-urban disparity and thereby the need to increase access and coverage of ophthalmic provision. The key barriers highlighted were cost, distance, time, and lack of awareness of the importance of timely detection and treatment. From the analysis of patient, stakeholder, and user views regarding Peek, it can be concluded that Peek offers an acceptable solution to overcoming barriers to access to eye care, fulfills the criteria for usability for HCPs, and acts as a means to strengthen eye care delivery. Peek is perceived to be valuable predominantly in increasing coverage in rural settings, thereby contributing to the third global goal for sustainable development [47]. As proposed by the HCPs and stakeholders, it is also likely to have a bearing on reducing burden on ophthalmologists who with the help of CHVs using Peek can now work remotely through task shifting. To successfully deploy Peek and achieve universal coverage, it is considered imperative to build a sustainable model by integrating and working with the government, local communities, and NGOs. Ongoing research would be required to evaluate the processes of deployment and to assess whether the benefits outlined translate to improved eye health outcomes and public health indicators.

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Conflicts of Interest

AB is Founder of the Peek Vision Foundation, a not for profit, UK registered charity, and a Director of its wholly owned trading subsidiary, Peek Vision Ltd.

Multimedia Appendix 1

Peek application screenshots.

[PDF File (Adobe PDF File), 678KB - mhealth_v4i2e30_app1.pdf]

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Abbreviations

CHV: community health volunteer
HCP: health care provider
HS: health system
mHealth: mobile health
MP: mobile phone
NGO: nongovernmental organization
Peek: Portable Eye Examination Kit
SMS: short message service
TAM: Technology Acceptance Model
VA: visual acuity
WHO: World Health Organization

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Original Paper

Mobile Health Insurance System and Associated Costs: A Cross-Sectional Survey of Primary Health Centers in Abuja, Nigeria

Emeka Chukwu[1], BEng (Hons), MSc; Lalit Garg[2], PhD (Ulster), PGDIT, BE; Godson Eze[3], MBBS, MPH, MHPM, Cert. SRH(GFMER), FMCPH

[1]University of Liverpool, Faculty of Computer Science and Engineering, Liverpool, United Kingdom

[2]University of Malta, Faculty of Information and Communication Technology, Msida, Malta

[3]Delta State University Teaching hospital (DELSUTH), Department of Community Medicine, Oghara, Delta State, Nigeria

Corresponding Author:
Emeka Chukwu, BEng (Hons), MSc
University of Liverpool
Faculty of Computer Science and Engineering
Liverpool
Mercy side
Liverpool, L69 3BX
United Kingdom
Phone: 44 8037760629
Fax: 44 8037760629
Email: emeka.chukwu@online.liverpool.ac.uk

Abstract

Background: Nigeria contributes only 2% to the world's population, accounts for 10% of the global maternal death burden. Health care at primary health centers, the lowest level of public health care, is far below optimal in quality and grossly inadequate in coverage. Private primary health facilities attempt to fill this gap but at additional costs to the client. More than 65% Nigerians still pay out of pocket for health services. Meanwhile, the use of mobile phones and related services has risen geometrically in recent years in Nigeria, and their adoption into health care is an enterprise worth exploring.

Objective: The purpose of this study was to document costs associated with a mobile technology–supported, community-based health insurance scheme.

Methods: This analytic cross-sectional survey used a hybrid of mixed methods stakeholder interviews coupled with prototype throw-away software development to gather data from 50 public primary health facilities and 50 private primary care centers in Abuja, Nigeria. Data gathered documents costs relevant for a reliable and sustainable mobile-supported health insurance system. Clients and health workers were interviewed using structured questionnaires on services provided and cost of those services. Trained interviewers conducted the structured interviews, and 1 client and 1 health worker were interviewed per health facility. Clinic expenditure was analyzed to include personnel, fixed equipment, medical consumables, and operation costs. Key informant interviews included a midmanagement staff of a health-management organization, an officer-level staff member of a mobile network operator, and a mobile money agent.

Results: All the 200 respondents indicated willingness to use the proposed system. Differences in the cost of services between public and private facilities were analyzed at 95% confidence level ($P<.001$). This indicates that average out-of-pocket cost of services at private health care facilities is significantly higher than at public primary health care facilities. Key informant interviews with a health management organizations and a telecom operator revealed high investment interests. Cost documentation analysis of income versus expenditure for the major maternal and child health service areas—antenatal care, routine immunization, and birth attendance for 1 year—showed that primary health facilities would still profit if technology-supported, health insurance schemes were adopted.

Conclusions: This study demonstrates a case for the implementation of enrolment, encounter management, treatment verification, claims management and reimbursement using mobile technology for health insurance in Abuja, Nigeria. Available data show that the introduction of an electronic job aid improved efficiency. Although it is difficult to make a concrete statement on

profitability of this venture but the interest of the health maintenance organizations and telecom experts in this endeavor provides a positive lead.

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KEYWORDS

mobile health; mHealth; eHealth; health financing; health insurance; public health informatics

Introduction

Background

This study aims to document costs associated with and provide justification for adoption of mobile phone as an alternative to drive the uptake of community-based health insurance schemes (CBHIs). Studies have shown that one of the biggest challenges of health care systems in developing countries is financing [1]. Data from World Bank puts the percentage of persons living on less than a dollar a day in Nigeria at 68.0% [2]. The Presidential Task Force on maternal health in Nigeria, in a randomized research, found that 30% of participating pregnant women could not use maternal health services owing to their inability to pay [3]. The government remains the single major financier of health systems in Nigeria. Nigeria has slightly more than 21,808 public primary health centers (PHCs) as compared to 8290 private PHCs [4]. These numbers exclude the secondary and tertiary health facilities.

On the basis of current health insurance coverage estimates, most clients settle payments for health services out of pocket at point-of-service [5]. "Evidence from other developing countries have shown that catastrophic health spending can push people into poverty" [6]. Reasons for poor health insurance enrolment despite its potential for risk pooling has been the subject of much research [7-9]. Reimbursement methods adopted have equally been a source of debate [9]. Because capitation considers the volume of clients serviced for a period, the clients might not get optimum quality of care, thus adversely reducing patient health and satisfaction and subsequently, health outcome [10]. Other schools of thought dictate that the fee-for-service method has resulted in "overtreatment," with multiple patient visits required for services [9]. Business experts on the other hand are looking for a "sweet spot" in this dilemma [11]. This may be the reason why Nigeria's health insurance regulator, the National Health Insurance Scheme (NHIS), allows for a use of a hybrid of the two [5].

Nigeria's Health Insurance Adoption

The NHIS was setup to provide a regulatory framework to support the social health insurance system for Nigerians [5]. The NHIS puts the current insurance adopters at less than 4 million of the country's total population of about 170 million [5]. This is less than 3% of the country's population. This is quite poor when compared to that of Ghana, with a total population of 25 million and more than 14 million persons enrolled in 3 years [12]. These statistics indicate that the NHIS fell short of its target of 30% coverage by the end of 2015 as mandated by the Nigerian president [5]. The scheme recently issued a guideline for CBHI [13], proposing community prepayment and a not-for-profit model as the preferred method. States of the federation have also been authorized to run state-based health insurance schemes. Many communities and states currently do not possess the capacity to sustainably manage and track the complexity of an insurance scheme [8]. As a result, adoption has been very low, and the few CBHI pilots have not scaled. A scalable CBHI needs to solve the problem of premium tracking, management, and accountability. And technology has been shown to improve accountability and transparency [14]. If properly applied, technology has the potential to solve many of the thorny issues bedeviling the CBHI's adoption at scale.

For the purpose of this study, all discussions referencing health insurance will refer to the CBHI hybrid focusing on maternal and child health. Various models of this scheme exist, one type, taking its operational model from its name, is organized and managed by community members through a committee sometimes called "Ward Development Committee"[15]. The committee manages drug purchases and other health facility spending. The premium is set by the community and maintained by committee members. It is also the responsibility of the committee to keep track of claims and spending and report back to the general community meetings [5,16,17]. This scheme has been piloted at different times in Lagos, Jigawa, Anambra, and Abuja. Some regions struggle to continue implementing the scheme after the initial pilot, whereas others stopped at the end of the pilot phase [7,17]. The current costing model covers health maintenance organization (HMO) administrative costs, NHIS administrative costs, capitation fees for the PHCs, and fee-for-service fees for secondary and tertiary health facilities [5]. The guidelines further stipulate that communities seeking to join the CBHI scheme should have more than 1000 enrollees or more than 50% of its population ready to enroll. NHIS has not fixed premium and reimbursement rates for CBHI. However, a pricing template is provided to guide the HMOs and the health facilities in reaching an agreement.

Primary Health Centers in Abuja

Maternal and child health domain of PHCs in Abuja, Nigeria, was the scope of this work. Treatment received at a referral center was excluded to reduce complexity.

Abuja is the federal capital territory (FCT) of Nigeria. Its population is 2.29 million [4]. The health care structure in Nigeria is such that the federal government is responsible for the tertiary health facilities through the federal ministry of health and the state governments for the secondary health facilities through their hospital management boards, while the PHCs are the responsibility of the local government areas (LGAs). The directory of health facilities in Nigeria puts the number of PHCs in FCT at 559, and only 179 (32%) of these are publicly owned [4]. Abuja is administratively grouped into 6 area councils,

equivalent of LGAs in the states of the Nigerian federation. Area councils in Abuja ideally manage these 179 public-owned PHCs. They provide operational and logistics support. The staff salaries of these PHCs are also the responsibility of the area councils [3].

Digital Health

There has been a massive growth in and adoption of mobile phone and related services in Nigeria over the last decade [18]. Data from Nigerian Communications Commission show that Nigeria is one of the fastest growing markets for mobile telephony, with penetration near 90% and over 121 million active GSM lines as of September 2013 from 240,000 lines at inception in 2001 [18,19]. The growth of this technology has given rise to various uses such as car tracking, remote home surveillance systems, and many more, and this has since been extended to health care. This presents an opportunity to reach a larger proportion of the underserved with mobile technology-supported health services, particularly for insurance uptake. Many have already adopted this for health information and education through short message service (SMS) text reminders, and there is overwhelming evidence to show that adherence to drugs and hospital attendance improved with SMS text message reminders [20]. Although there is limited evidence on how the use of mobile technology beyond SMS can be linked to health outcomes [21], electronic medical records have been shown to reduce costs and errors [22]. Kumar and Bauer [22] also argued that it is possible to mine treatment data and other information from a properly implemented electronic health record system. Nigeria recognized the potential technology has to meet the ambitious Millennium Development Goals 4, 5, and 6. This culminated in the launch of the Saving of One Million Lives initiative [23]. At the launch of the initiative in December 2012, the government announced a partnership with mHealth Alliance to use information communication technology to support this initiative [24]. Kai-Lik Foh, Mobile Health Manager at the Association of GSM telecommunications operators suggested the application of mobile technology for health insurance in his 2011 article [25]. He listed the various stakeholders: payers, providers, purchasers, producers, and so forth. However, 3 years after this work, to our knowledge, no single paper on an operational or prototype system addressing this exists in the public domain.

Methods

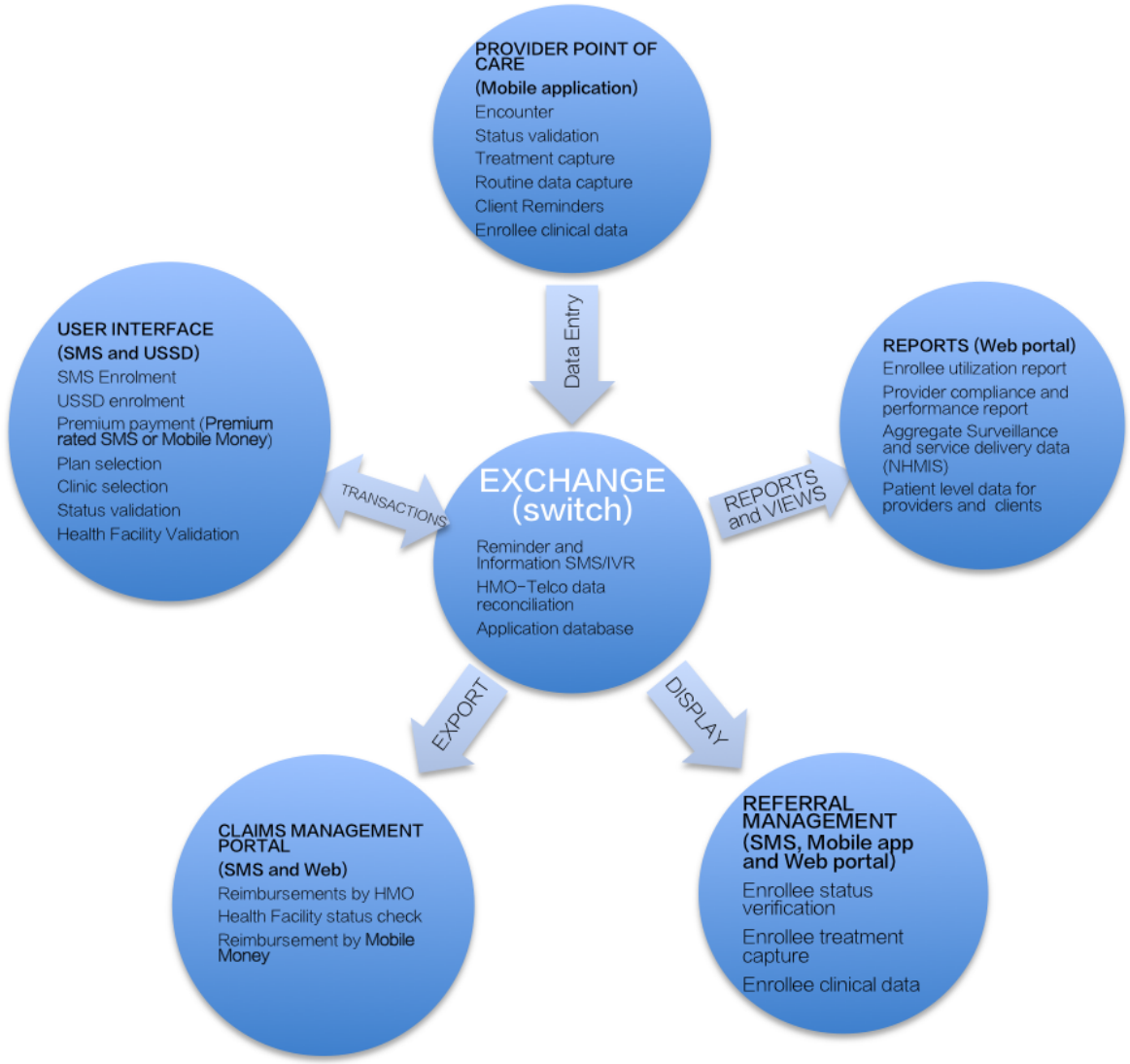
Ethical Approval

This research was the output of the principal investigator's masters level dissertation studies. Data collection and analysis were conducted between December 2013 and February 2014. The Research Ethics Committee of the University of Liverpool, United Kingdom, approved this study.

Design

This study is an analytic cross-sectional survey, which used a hybrid of mixed methods, involving key informant interviews supported by a "throw-away' prototype software demonstration. A review of the current literature was conducted to guide the appropriateness of the approach. Health facility clients and health care providers were interviewed using structured questionnaires. The income and expenditure at both the private and public PHCs were analyzed. A client and a provider were interviewed in each health facility visited. Fifty public and 50 privately owned PHCs were considered representative of the study area. A throw-away prototype software system was designed to guide respondents' understanding of the electronic enrolment and encounter systems. The prototype software conceptual framework is shown in Figure 1. The software structure shows a combination of 5 different subsystems with special focus on end-user requirements. At the time of interview, only the "CommCare mobile point of care" was functional in this multifunctional system. This was sufficient for demonstration of the software to the health workers for interview purposes. The software setup and running costs were extrapolated using the software development life cycle methodology. Similarly, the out-of-pocket costs paid for health services were also documented to assess the current income of the PHC. The willingness to pay result was used to extrapolate proposed income per health facility. An assumption in the income extrapolation was that the outpatient visits would record 50 visits for various consultations per month.

Figure 1. Prototype Software Conceptual Framework.



Recruitment

Two structured questionnaires were used for health facility clients' (n=100) and the health workers' (n=100) interviews. One hundred PHCs were randomly selected and visited by the research assistants. Fifty each of private and public primary health facilities were purposefully sampled to provide representative spread across public and private PHCs. The participant information sheet and the informed consent forms were read to the clients/health workers and health workers, and the consenting clients were interviewed after appending their signatures. One client and one health care provider were interviewed in each PHC visited. Interviewed clients had to be aged 18 years or older and must have received antenatal, immunization, or delivery service in the health facility visited. Client selection was on the first contact basis. Clients not meeting these criteria were excluded from the study, and the next available client was assessed and interviewed. The health worker interviewed was the most senior officer in the health facility at the time of visit by research interviewers. For confidentiality, all identifiable information was excluded from the questionnaire; to ensure data validity and reduce bias, research assistants and interviewers were enlightened on the objectives of the research and trained on how to ask and obtain answers for each of the questions to reduce bias and interobserver variation, as they were not supervised during the interviews. The health facility and LGA codes were adapted from the directory of the health facility [4].

The client questionnaire had 26 questions, which were grouped under 3 parts: A, B, and C. Part A of the client questionnaire contained questions that related to the reliability of the services in the health facilities. Information on the "time of last visit" was used to measure the frequency of health facility visits. Although the frequency of client falling ill and other factors might be beyond the scope of this research, these data were necessary to document costs necessary for good return on investment of any system targeting the primary health facility. Client's perception of the service provided was captured using the "service rating" question. This was also validated using the "willingness to recommend others to the health facility," question, as it is expected that a client would only be willing to recommend others to the service if it was above average by their rating. This might not necessarily be an accurate measure of quality, as other factors may have influenced the response.

Part B of the questionnaire captured the cost of services provided by asking questions about "amount spent" during the current visit, the service provided, and whether drugs were provided. Knowledge of NHIS and the willingness to enroll were also assessed in this section. Interviewers were trained to rephrase the NHIS questions if the need arose. Each interviewed client was asked about the premium they are willing to pay.

Part C only tested the current capacity of the client to use mobile technology and phone ownership. Clients where asked if they owned a mobile phone and how long they have owned and used a mobile phone. Their ability to send structured text messages using SMS was also assessed in this section of the questionnaire.

Similarly, the health worker's questionnaire had 3 parts: A, B, and C. Part A asked questions to ascertain the reliability of service in the health facility. They were interviewed about their years of experience. They also responded to how satisfied they were with services provided in the PHC and how satisfied they perceive the community members are with the services provided. This section assessed the staff strength, which is a measure of the human resource capacity in a PHC. It has a direct bearing on the quality of service. Human resource is also a factor of the cost of providing service in a health facility.

Part B assessed the cost of services at the facility. The questions "drugs given," "cost of antenatal care," "cost of outpatient department," and "cost of delivery" were all used to ascertain and document the eventual cost of services in the health facilities. Their awareness and knowledge of NHIS was also assessed in this section. Part C assessed the health worker's phone ownership and capacity for using phone for SMS and other applications.

Similarly, key informant interview was conducted for a midmanagement HMO representative, an officer-level staff of a mobile network operator, and a mobile money agent.

Statistical Analysis

The survey data were analyzed using Statistical Package for Social Sciences software (version 22) [26]. Descriptive statistics using the cross-tabulation functionality in most cases were used for the analysis. The analysis considered the study hypothesis that mobile health insurance was both reliable and sustainable and requires adequate cost documentation to demonstrate investment case. The operations of the current PHCs were analyzed and triangulated against the interview data from the clients and health workers. The cost-based price model based on time and material as described by Heizer and Render [27] was used to compare expenditure and income to help arrive at a costing model. The cost incurred by a health facility, private or public, was classified into 4 groups: personnel, fixed equipment, medical consumables, and operating costs. The operating cost was further divided into 4 subsections. But medical consumables were not collected during this study. Further details of the results are discussed in the Results section.

The responses were thematically analyzed in relation to reliability and sustainability indicators [28,29]. The costs of antenatal, delivery, and immunization services were analyzed for variance in mean between public and private primary health care facilities. The variance was also tested for significance using the Student *t*-test at a confidence level of 95%.

Results

Demographic Characteristics

All 100-client respondents were expectant or new mothers; 51 (51%) were aged 18-34 years, 48 (48%) were aged 35-49 years, and only 1 (1%) was aged more than 50 years.

Only 25% of clients had visited a health facility in the last month, and 32 (32%) in the last quarter. Fifteen (15%) had visited a health facility within 6 months and 18 (18%) within the last year; 10 (10%) had not visited any health facility in over a year. Twenty-three (23%) of interviewed women had not been sick for over a year, and 26 (26%) were sick between 6 and 12 months.

Table 1. Clients' mean last clinic visit and last period of illness in months by age group.

Age group (years)	Mean last clinic visit (months)	Mean last period of illness (months)	n (%)
18-34	4.12	6.48	51 (51)
35-49	2.61	7.30	48 (48)
≥50	24.00	1.50	1 (1)
Total	3.01	6.34	100 (100)

Service Rating

Figure 2 shows moderate variations in service perception rating between respondents in public PHCs and private PHCs: 94% of respondents said the service was between "somewhat-good" and "very good" in public PHCs. This is considered a measure of reliability of the operation, and a mobile app–based health insurance enrolment system could benefit from this perception-based vote of confidence. Although other factors might have influenced this output, the proportion of clients who would recommend the clinics to others was 89%.

The health facility staff strengths were also analyzed, as depicted in Table 2; 53 (53%) of interviewed health facility staff members were female.

Table 2. PHC type and staff strength in Abuja (N=100).

PHC[a] type	1-5 Staff n (%)	6-10 Staff n (%)	≥11 Staff n (%)	N (%)
Public PHC	5 (10)	7 (14)	38 (76)	50 (100)
Private PHC	6 (12)	20 (40)	24 (48)	50 (100)
Total	11 (11)	27 (27)	62 (62)	100 (100)

[a]PHC: primary health center.

Figure 2. Service rating by clients.

Cost Documentation

The monthly expenditures incurred by PHCs were grouped into personnel, operations, fixed equipment, and medical consumables costs. The personnel expenditure primarily included clinical and nonclinical staff time; fixed equipment costs; and covering equipment such as couches, beds, building, and so forth. The operation cost was further subdivided into power, water, paper printing, and transportation costs. The private PHCs are entirely self-funded for all categories of expenditure, whereas their public equivalents have personnel cost completely covered and receive unstructured government subsidy for operations. The level of subsidy depended on various factors such as the proximity of the health facility to the client, client load, and even political interests. In other cases, some of the public health facilities do not receive subsidies.

On the other hand, the health facility income stream was analyzed based on responses from clients and health workers. The results of the analyses are summarized in Table 3. These income streams were categorized by health facility and service type. Table 3 shows a wide variation between out-of-pocket cost of service in public and private PHCs for the 3 services surveyed. The service costs were enquired as a range instead of a discreet amount to address privacy concerns. None of the 100 clinics visited were accepting clients on any form of insurance.

Table 3. Service costs as reported by health facility staff interviewed.

PHC ownership	Cost of antenatal service ( ) (*P*<.001)	Cost of OPD[a]consultation ( ) (*P*<.001)	Cost of delivery service ( ) (*P*<.001)
Public			
n	50	50	50
Mean	444.5	435.5	426.5
Standard deviation	541.2231	539.7704	538.1601
Private			
n	50	50	50
Mean	2691.44	2008.46	2691.44
Standard deviation	1472.0359	1538.7633	1472.0359
Total			
N	100	100	100
Mean	1567.97	1221.98	1558.97
Standard deviation	1578.7391	1393.1766	1584.7048

[a]OPD: outpatient department, PHC: primary health center.

The cost of service as reported by the interviewed health workers, shown in Table 3, varied widely between the private PHCs and public PHCs. This difference was consistent across the 3 services assessed.

Table 4. Amount spent for health service on clinic visit day.

PHC ownership	Amount spent at clinic today ( ) (*P*<.001)	Premium willing to pay ( ) (*P*>.99)
Public		
n	50	50
Mean	1691.42	2380.270
Standard deviation	1953.861	1736.8265
Private		
n	50	50
Mean	4291.04	2380.350
Standard deviation	2663.122	1427.1472
Total		
N	100	100
Mean	2991.23	2380.310
Standard deviation	2665.777	1581.4980

Similarly, client responses to amount spent for health service as shown in Table 4 also varied widely between private and public PHCs. In contrast, clients in private and public health facilities are willing to pay similar average for family insurance premium as is indicated by *P*>.99. This average amount they are willing to pay is lower than current premium costs. Service costs, particularly for antenatal service, were significantly different in both public and private PHCs as shown by *P*<.001, and any difference cannot be attributed to chance. This difference is clearly demonstrated in Figure 3.

As shown in the figure, the clients interviewed at the public PHCs spent less than those at private PHCs. On the interview day, 21 clients (41%) in public versus 1 (2%) in private PHCs reported spending between 100 and 500. The other extreme also shows that half of the clients (n=25; 50%) at private clinics indicated spending more than 5000 on the interview day, whereas only 4 clients (8%) reported doing the same in public clinics.

The client interview data for premium affordability and willingness to pay for families were marginally different from health provider interviews, as shown in Figure 4.

Table 5. Services provided by PHC[a]type.

Service provided	Private PHC (%)	Public PHC (%)	n (%)
Antenatal attendance	25 (50)	23 (46)	48 (48)
Immunization attendance	12 (24)	24 (48)	36 (36)
Delivery attendance	13 (26)	3 (6)	16 (16)

[a]PHC: primary health center.

Estimates provided in Table 6 are costs documentation averages based on key informant interviews for a fully functional software system. The prevailing inflation and current cost of services were factored in this computation. This, in reality, of course may vary from vendor to vendor and depending on the sophistication of different systems. The 5-year cost expenditure for a fully functional PHC software system was estimated to be $115,425. This was on the assumption that each facility will deploy a cloud computing software system. This can be significantly lower when an LGA for instance pools resources to cover the initial capital investment across board.

Table 6. Software setup and operation expenditure.

Year	Seed fund expense	Estimate ($)
Year 1 (Immediate)	One-time software setup	29,800.00
	One-time infrastructure cost and cloud computing setup cost	50,000.00
	Yearly support and maintenance	10,000.00
	Training software administrator	31.25
	Other personnel costs	20,000.00
	Total estimated seed fund for software	109,831.25
Year 1	Annual PHC[a]expense	
	Annual data and SMS ($18.72 × 2 × 12)	450.00
	Mobile device (10″ tablet)	562.50
	Spare mobile device	562.50
	Annual device replacement (20% device value)	112.50
	Annual electricity for device charging	300.00
	Training of 5 PHC staff members	156.25
	Total year 1 cost per PHC	2,143.75
Years 2, 3, 4, and 5[b]	Annual data and SMS ($18.72 × 2 × 12)	450.00
	Annual device replacement (20% device value)	112.50
	Annual electricity for device charging	300.00
	Total 1-year recurrent cost per PHC	862.50
	4 Year Recurrent cost	3,450.00
	Total 5-year cost per PHC	115,425.00

[a]PHC: primary health center, SMS: short messaging service.

[b]Yearly recurrent cost.

Excluding drugs and other medical supplies, other annual expenditure expected per PHC for personnel cost and operation costs detailed in Table 7. These estimates were obtained from the prevailing electricity cost and generator fueling costs. Excluding medical consumables does not directly affect the cost of running a digitalized PHC, as it has no effect in this cost-documentation exercise.

Table 7. Personnel and operation expenditure of a primary health center[a].

Serial number	Monthly expenditure	Unit annual rate ($)	Number of personnel	Amount ($)
1	Clinical and nonclinical personnel	3,750	10	37,500
2	Operation costs			1875
	Total			39,375

[a]Excluding medical consumables in a digitized primary health center, as it has no effect in this cost-documentation exercise.

Operational costs summarized in Table 7 can be categorized into system management, transaction fees, hardware and software maintenance, training, and software usage support. The income stream for each PHC can be computed for antenatal and delivery based on their current service rates as received from the interviews. As listed in Table 3, the mean cost of antenatal services is 444 ($2.2) for public PHCs and 2691 ($13.5) for private PHCs. On the basis of conservative estimates based on key informant interviews with key stakeholders, 50 clients per month per health facility was used to compute the estimated enrolment income. Key informant interviews quoted monthly client load for PHCs as being between 50 and 600 clients, and we assumed that 25 deliveries would be an appropriate estimate per health facility. If the income per health facility is based on the health insurance enrolment for recommended minimum 1000 persons/families. At the proposed estimate for willingness to pay that is at 2380 ($11.9) per family per month. The annual premium income from each family will add up to 28,560 ($143.5) if they are charged the average amount they are willing to pay (Table 4). This means that for any PHC that has up to 1000 families enrolled for their insurance, the annual premium income will add up to $143,500.

The key informant interview with a midmanagement HMO representative indicates that they reimburse for services using a combination of fee-for-service and capitation within 30 days of claims submission. The 30 days allows for vetting and verification. The most common reason for delayed reimbursement was “missing or incomplete detail.” The main reason for client service denial was attributed to misunderstanding of service level availability for selected plans and list of hospitals including those for referrals. They noted that enrollees complain most about perceived “substandard drugs” given as against out-of-pocket payees. Health facilities are currently reimbursed through bank wire irrespective of location. This HMO indicated that the most basic package for a family of 4 per annum costs 90,000 ($452). When enquired if they encourage monthly premium payments, the response was no. On the other hand, an individual will have to enroll with a premium in the range of 20,000-450,000 ($100.5-$2261.3), depending on service coverage and hospital selection.

Although a formal interview with a representative of a mobile network operator could not be conducted or because of several reasons, in an informal interview, an officer level staff explained that it is possible to enroll for health insurance using SMS or unstructured supplementary service data and that it is a part of business priority interest for his organization. Similarly, a mobile money agent interviewed to assess the viability of premium payment and service reimbursement to health facilities through mobile money indicated that mobile money business was neither lucrative nor widespread in reach to support the enterprise.

Figure 3. Comparison of private and public service expense cost by health facility.

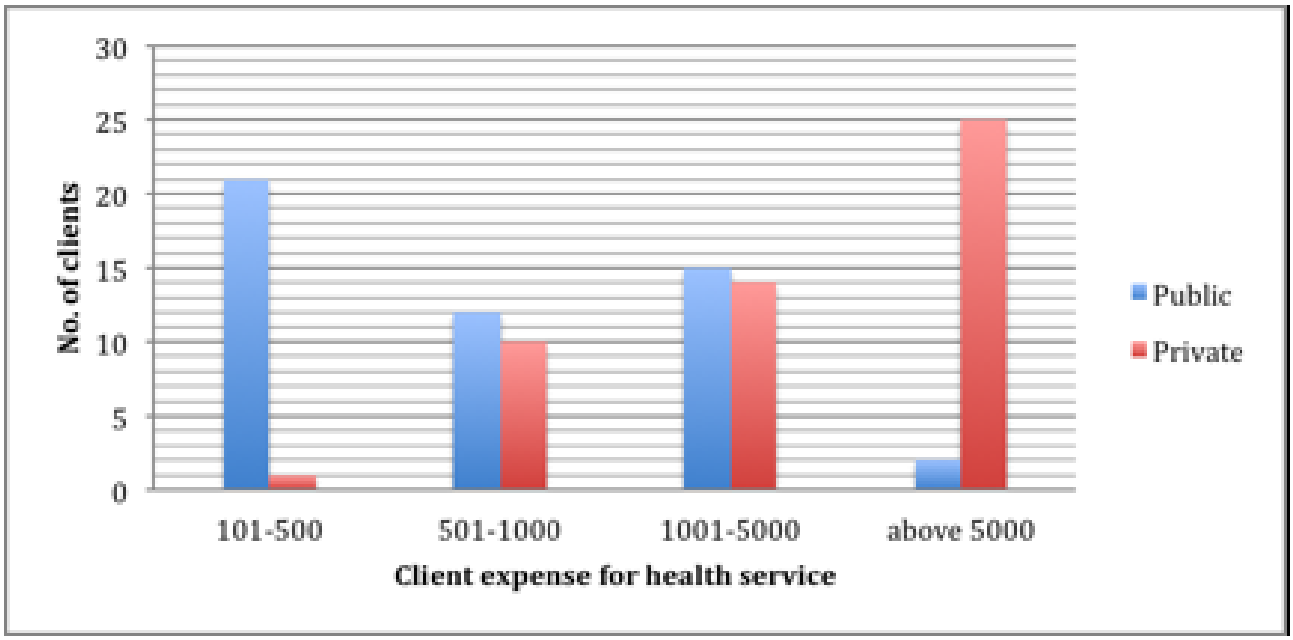
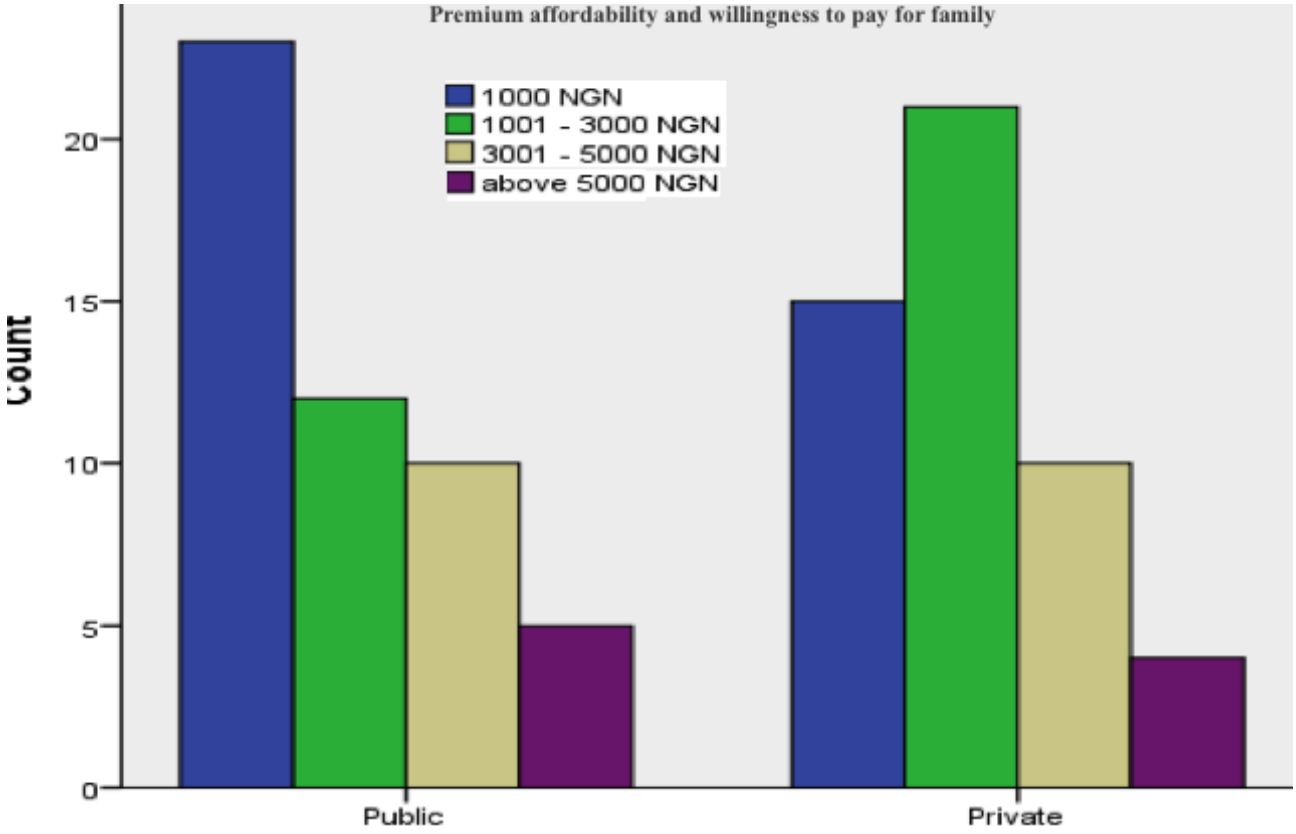


Figure 4. Premium that the interviewed clients are willing to pay per family per annum.



Discussion

The major findings from this study are that there is wide disparity in cost of payment for health services between private and public PHC institutions in Abuja, Nigeria. The results show that the deployment of a mobile-supported scalable insurance scheme will require significant investment to set up and operate. The interviews indicate that although services are not at an optimal level, clients are generally happy with the service they currently receive. This, we believe, may be related to their experience and exposure. The results of a recent survey conducted by Sambo et al in Kaduna State in north-western Nigeria were consistent with the results of this study on maternal neonatal and child health service costs [30]. However, Sambo et al only focused on public PHCs in their research. Our results are consistent with those of a similar study conducted by Pathfinder International, showing that the use of point-of-care mobile app can significantly improve quality of care in Abuja, Nigeria [31]. In the same study, the Pathfinder International team demonstrated that a significant number of the health workers were happy using the electronic point-of-care tool as against using paper forms. However, the low cost of services at public PHCs has often been associated to the low quality of care provided. This also explains why although the private PHCs charge more than 200% when compared to their public equivalent, the number of deliveries conducted in the private hospitals still remains at almost 4 times of that in public PHCs, as can be seen in Table 4. The effect of introducing mobile health insurance in primary health facilities in Abuja, Nigeria, can be assessed through the implementation of existing health information communication technology, adopting a model similar to the proposed model [31]. The pilot of CommCare point-of-care decision support by Pathfinder International in some facilities in Abuja and Nasarawa, Nigeria, demonstrated that health facility operations were not affected negatively by the introduction of point-of-care technology [13]. We build our premise on this: the introduction of digital job aid is not likely to reduce the reliability of services of the health facilities using it. Other factors are proximity of the PHCs to the client's residence, irregular supply of drugs and consumables, and so forth. Of the health facility representatives interviewed, 62% indicated having 11 staff members or more, and this was consistent for both private and public PHCs. This however does not always translate to improved quality of care. Visits to these health facilities often show striking contrasts, with not more than 3 staff members at any given time. It was not clear why this is so; however, key informant interviews suggested duty rotation as a possible cause. Another factor worthy of note is that the available data do not distinguish between midwives and community health extension workers, which might be of interest for a future study.

The key informant interview with the HMO showed that the current premium pricing may not be realistic, as only 10% (n=10) of clients interviewed were willing to pay a cumulative of 20,000 ($100.5) per family per annum. The HMO reportedly charges this minimum per individual and about 100,000 ($502.5) per family, when we consider that many public health facilities may still need a significant initial investment to meet certain service delivery quality standards that will drive demand for health services. The need for alternate and seed funding becomes important for improving both infrastructure and quality level and to subsidize the premium pricing.

In February 2013, a leading Nigerian newspaper, the *National Mirror*, published an article showing that Nigerian telecommunication subscribers spent as much as 1.28 trillion ($6.4 billion) in the year 2012 for voice communications alone [32]. If the current call rates are taxed an additional 0.01 (equivalent of $0.00005), as opposed to the current 0.30 per second for calls within the country, a whopping income of 170 billion ($854 million) will be generated annually. This fund, when properly managed, can be used to fill the gap the seed funds were expected to fill and alleviate the quality concerns in participating PHCs across the country. Furthermore, when quality improves, demand is expected to increase, and as such, insurance alongside its mobile-supported management mechanism can be easily sold. However, this is only an assumption, as it requires political support for effective implementation. Seed funding to improve current PHC infrastructure can also be acquired through donor funding. Others have advocated for sin tax to bridge this gap.

The Nigerian government has provided a minimum of 1% of its consolidated national funds for health care through the National Health Law 2014 [33]. Both NHIS and National Primary Health Care Development agency statutorily receive more than 50% of this fund. This fund can support the infrastructure and lay adequate foundation for a mobile-supported, CBHI and point-of-care service. Funds such as the aforementioned will make health and application of mobile technology to health care both profitable and equitable.

Limitations

During this study and analysis, the cost of health services at the referral facility (secondary and tertiary health facilities) was assumed to be the same as in the primary health facility and the mean computed from the interviews. However, this is not always so, as the treatment increasingly becomes expensive as we move from primary care to secondary to tertiary. The income analyses were conducted using out-of-pocket payment extrapolation. The actual proposed income profile will vary slightly based on insurance enrolment and buy-in by each community. According to Abuja FCT, millennium development goals office, drug supplies to these public health facilities have often been inadequate [34]. This is often worsened by the poor commodity logistics at this level of care in the country. Investigations through informal discussions show that these hitherto insufficient drugs are sometimes wasted because of poor logistics. The health facility staff then makes up for these shortfalls by adopting a widely known method locally called "drug revolving." In this method, they are allowed to buy drugs to augment supplies from the government and use generated funds to maintain drug supply in the health facility; however, they are not expected to make profits. Inconsistency in supply of these drugs, which sometimes do not reach the health facilities, and other equipment and structural variations makes it pertinent for treatment price to vary from health facility to health facility. This variation can even be wider between public and private PHCs. This poses a huge challenge for uniform pricing and particularly for premium determination. This is critical as NHIS is emphasizing its social insurance role and angling towards mandatory health insurance with the states as drivers. Moreover, statistics available show that private practitioners bear the burden of a larger percentage of the population in Abuja, Nigeria, at this level of care under consideration in FCT, as they own 68% (380 of 559) of the PHCs [4]. The assumption that a seed fund can help fill the identified gap also recognizes that there are other sectors (Agriculture, Education, Environment, Power etc) competing with health for priority investment and will have to harmonize asks for effectiveness.

Conclusions

Mobile health insurance presents an opportunity for wider expansion of insurance adopters. It was easy to establish that a mobile enrolment system will improve efficiency and reliable. The interests demonstrated by mobile network operators and health management organizations demonstrate business interest and willingness to participate. However, profitable cost for identified stakeholders would hover around the private PHCs' mean service costs, still requiring significant subsidy. This means that to achieve universal health coverage, insurance costing model must consider identified variations. This study successfully demonstrated that mobile supported enrolment, encounter management, treatment verification, and claims management and reimbursements can be efficient and sustainable. It also shows that using technology can aid in accountability and thus reliability of CBHI financing and reimbursement. This study successfully documented income and expenditure associated with personnel, fixed equipment, and operation, as they influence the adoption of mobile insurance-management system. Costs for medical consumables have been a topic of many other researches and were not considered in this study.

Conflicts of Interest

None declared.

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Abbreviations

CBHI: community-based health insurance
FCT: federal capital territory
GSM: Global System for Mobile Communications
HMO: health maintenance organization
LGA: local government area
NHIS: National Health Insurance Scheme
PHC: primary health center

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Original Paper

Are Text Messages a Feasible and Acceptable Way to Reach Female Entertainment Workers in Cambodia with Health Messages? A Cross-Sectional Phone Survey

Carinne Brody[1*], MPH, MA, Dr PH; Sukhmani Dhaliwal[2*], MPH (current), DO (current); Sovannary Tuot[3*], MA; Michael Johnson[2*], MPH (current), DO (current); Khuondyla Pal[3*], MHS; Siyan Yi[2,3*], PhD, MD

[1]Touro University California, Public Health Program, Center for Global Health Research, Vallejo, CA, United States

[2]Touro University California, Public Health Program, Vallejo, CA, United States

[3]KHANA, Center for Population Health Research, Phnom Penh, Cambodia

[*]all authors contributed equally

Corresponding Author:
Carinne Brody, MPH, MA, Dr PH
Touro University California
Public Health Program
Center for Global Health Research
1310 Club Drive
Vallejo, CA, 94592
United States
Phone: 1 7076388533
Fax: 1 7076388555
Email: carinne.brody@gmail.com

Abstract

Background: Despite great achievements in reducing the prevalence of HIV, eliminating new HIV infections remains a challenge in Cambodia. Entertainment venues such as restaurants, karaoke bars, beer gardens, cafes, pubs, and massage parlors are now considered important venues for HIV prevention efforts and other health outreach interventions.

Objective: The purpose of this study was to explore phone use and texting practices of female entertainment workers (FEWs) in order to determine if text messaging is a feasible and acceptable way to link FEWs to health services.

Methods: This cross-sectional phone survey was conducted in May 2015 with 97 FEWs aged 18–35 years and currently working at an entertainment venue in Phnom Penh.

Results: Of the 96 respondents, 51% reported sending text messages daily; of them, 47% used Khmer script and 45% used Romanized Khmer. Younger FEWs were more likely to report daily texting (P<.001). Most FEWs (98%) in this study reported feeling comfortable receiving private health messages despite the fact that 39% were sharing their phone with others. Younger FEWs were less likely to share their phone with others (P=.02). Of all of the FEWs, 47% reported owning a smartphone, and younger women were more likely to own a smartphone than were older women (P=.08).

Conclusions: The findings from this study support the development of mHealth interventions targeting high-risk groups in urban areas of Cambodia. Our data suggest that mHealth interventions using texting may be a feasible way of reaching FEWs in Phnom Penh.

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KEYWORDS

mHealth; short message service; Cambodia; female sex workers; HIV

Introduction

Despite great achievements in reducing the prevalence of HIV, eliminating new HIV infections remains a challenge in Cambodia. Cambodia is one of the few countries in the world that have reversed their HIV epidemic from generalized to concentrated; it is now confined mainly to individuals who engage in high-risk behaviors such as sex workers [1]. In 2013,

it was estimated that the HIV prevalence among the general adult population was 0.6%, reflecting a significant decline from the peak of 2.0% in 1998 [2]. This success was widely attributed to the "100% condom use" program targeting brothel-based commercial relationship, which led to a significant increase in condom use [3-6]. The passage and implementation of the "brothel ban" in 2008, an act that criminalized brothel-based sex work, may be making the situation more complicated because the sex trade has since gone underground, and more women have moved into indirect sex work through the entertainment industry, which is less stigmatized [7]. Entertainment venues include restaurants, karaoke bars, beer gardens, cafes, pubs, and massage parlors [8,9].

In Cambodia, as in many parts of Asia, a common pathway for young women from rural families is to migrate to urban areas to earn a better wage and send money back to their families [9]. Many young women migrate to the capital city to work in garment factories, which are the backbone of Cambodia's economy and employ more than 650,000 females [10], who typically begin working in the factories as teens [11]. These women and girls receive low pay, work long hours, and often struggle to navigate through the new social norms away from family oversight [12,13]. Owing to the poor wages, many seek to supplement or change jobs and move on to more lucrative jobs at entertainment venues. In these roles, many women begin engaging in one or more romantic relationships, which can involve direct or indirect transactional sex [14,15]. Therefore, entertainment venues are an important venue for HIV prevention efforts and other health outreach interventions.

Text messages (short messaging service, SMS) containing health service information and content advising health behavior change have the potential to be an inexpensive, discreet, adaptable, sustainable, and scalable way of reaching the vulnerable populations. Information about service locations and availability, live peer texting, and behavior change messages are some of the ways in which text messages can be used to increase use of critical services such as HIV testing.

Cambodia is the first country in the world in which the number of mobile phone users has surpassed the number using fixed line phones [16]. The number of mobile subscribers in Cambodia reached 20 million at the end of 2013, surpassing the country's population by about 5 million [17]. Mobile phone use by entertainment workers has increased at a similar rate and is now widespread among this population [18]. Worldwide, mobile phones are being used in developing countries to increase contraceptive use [19], improve pharmacovigilance [20], encourage diabetes self-management [21], collect health data [22], increase health knowledge [23], and increase adherence to treatment [24,25]. However, few mobile health (mHealth) interventions have been rigorously evaluated [23,26]. So far, there is rigorous evidence that mobile phone messages can be successfully used to support preventative health care [26-29]. Results from recent studies show that mHealth tools can also be successfully implemented in Cambodia in an urban setting [20], for HIV prevention [30] among young people, using participatory approaches [31-37].

Mobile health is still an emerging field, and new projects, particularly those in developing countries, face challenges. In Cambodia, we have identified a number of challenges for testing mHealth interventions. In terms of technical limitations, mobile users often own multiple subscriber identity module (SIM) cards in order to get cheaper in-network rates and better reception from the competitive phone networks in Cambodia, who also offer deals that entice users to use their SIM cards for a limited period of time [38]. Sharing phones with family members or neighbors, privacy concerns, and varying levels of literacy are additional limiting factors [39]. Furthermore, there is the added concern that most phones in Cambodia lack the ability to text in Khmer script, although the younger generation of tech-savvy Cambodians is more familiar with using a Romanized Khmer language for texting and social media.

The purpose of this study was to explore phone use and SMS practices in order to determine whether text messages are a feasible and acceptable way of linking female entertainment workers (FEWs) to health services in Cambodia.

Methods

The KHANA Center for Population Health Research reviewed and approved this study on May 15, 2015. The Institutional Review Board Committee of Touro University California approved the study on May 19, 2015 (IRB Application # PH-9015). All participants were informed of the study procedures and purpose and gave their verbal informed consent before participation.

This cross-sectional phone survey was conducted in May 2015. To be eligible for the structured survey, participants needed to be 18-35 years old, female, a mobile phone owner, and currently working at an entertainment venue in Phnom Penh, Cambodia. Three screening questions were used to determine eligibility: "what is your age," "do you currently work in the entertainment industry in Phnom Penh," and "do you currently own a mobile phone?"

A list of all FEWs living in Phnom Penh associated with KHANA, the largest national organization providing integrated HIV prevention, care, and support services in Cambodia, was generated by outreach workers working for KHANA's implementing partners. There were 135 women on the list. One hundred participants were randomly selected from the complete list of FEWs. If a participant did not meet the eligibility criteria or a phone number was no longer in use, another participant was randomly selected from the list. When the list was exhausted, we had managed to recruit 96 participants who were able to be interviewed.

Participants were recruited over the phone using a recruitment script that included screening questions. If they agreed to participate, they were given more information about the study, and their verbal informed consent to participate was required. Once they had given their consent, a structured interview was conducted over the phone. A structured closed-ended questionnaire was developed. The questionnaire covered demographics, text messaging practices, mobile phone use, and privacy concerns. The questionnaire was originally developed

in English and translated into Khmer, the national language of Cambodia. The hard copy document was converted into a Google Form to facilitate data input, which was done by multiple research assistants.

Descriptive analyses were conducted to describe participants' age, type of entertainment venue, and history of garment factory work using n (%) for categorical variables and mean (SD) for continuous variables. The chi-square test or Fisher exact test (when sample sizes were smaller than 5 in 1 cell) was used for categorical variables, and the Student *t* test was used for continuous variables to compare demographic characteristics, SMS use, phone use practices, and attitudes toward privacy and SMS between age groups (≤27 years vs. >27 years). STATA version 13 (StataCorp LP, Texas, USA) was used for all data analyses.

Results

A total of 96 FEWs participated in this study. Table 1 summarizes the demographic data. The mean age of participants was 27.3 years (SD 5.09). Half of the sample was over 27 years of age. Women worked as beer promoters (39%), restaurant hostesses (16%), karaoke girls (15%), sex entertainment workers (ie, in strip clubs, 15%), and masseuses (9%), as well as in other venues (7%). In total, 35% of participants had worked in a garment factory at some point in the past.

Table 1. Demographic data of study participants by age group (n=96).

Demographic variables		Total n (%) (n=96)	Younger FEWs [a] n (%) (≤27 years) (n=48)	Oder FEWs n (%) (>27 years) (n=47)	*P*
Age		27.33 (5)	23.0 (3)	31.7 (3)	
	>27 Years	48 (50)			
Type of entertainment work					.04
	Beer promoter	37 (39)	13 (27)	24 (50)	
	Restaurant hostess	15 (16)	10 (21)	5 (10)	
	Karaoke girl	14 (15)	8 (17)	6 (13)	
	Sex entertainment worker	14 (15)	11 (23)	3 (6)	
	Masseuse	9 (9)	2 (4)	7 (15)	
	Other	7 (7)	4 (8)	3 (6)	
Had worked in a garment factory		23 (35)	10 (35)	13 (36)	.96

[a]FEW: female entertainment worker.

Table 2 summarizes data on SMS use. When asked whether they had ever sent a text message, 53% said that they had. Of those, 69% reported sending more than 1 message per day, 22% reported sending about 1 per day, and 10% sent less than 1 per day. When asked what language they used most often when sending text messages, 47% reported using Khmer script, 45% reported using Romanized Khmer, and 8% reported using English.

Table 2. Use of short message service by study participants by age group (n=96).

Short message service variables		Total n (%) (n=96)	Younger FEWs[a] n (%) (≤27 years) (n=48)	Older FEWs n (%) (>27 years) (n=47)	*P*
Have you ever sent a text message on a mobile phone?		51 (53)	37 (77)	14 (29)	<.001
How often do you currently send text messages?					.32
	About 1 per day	11 (21)	6 (16)	5 (36)	
	More than 1 per day	35 (69)	27 (73)	8 (57)	
	Less than 1 per day	5 (10)	4 (11)	1 (7)	
What language do you use most often to send text messages using a mobile phone?					.21
	English	4 (8)	4 (11)	0 (0)	
	Khmer	24 (47)	15 (41)	9 (64)	
	Romanized Khmer	23 (45)	18 (49)	5 (36)	

[a] FEW: female entertainment worker.

Table 3 summarizes participants' mobile phone use practices. Of all respondents, 77% owned at least 1 mobile phone, 21% owned 2 mobile phones, and 2% owned 3 mobile phones. When asked about SIM card use, 62% reported currently using 1 SIM card, 37% used 2, and 2% used 3. When asked about the phone that they used most often, 53% of respondents reported using a regular mobile phone and 47% reported using a smartphone.

Table 3. Mobile phone use of study participants by age group (n=96).

Mobile phone use variables		Total n (%) (n=96)	Younger FEWs[a] n (%) (27 and under) (n=48)	Older FEWs n (%) (Over 27) (n=47)	*P*
How many mobile phones do you own right now?					.32
	1	74 (77.1)	34 (70.8)	40 (83.3)	
	2	20 (20.8)	13 (27.1)	7 (14.6)	
	3	2 (2.1)	1 (2.1)	1 (2.1)	
How many SIM cards do you use right now?					.98
	1	59 (61.5)	30 (62.5)	29 (60.4)	
	2	35 (36.5)	17 (35.4)	18 (37.5)	
	3	2 (2.1)	1 (2.1)	1 (2.1)	
When thinking of the mobile phone you use most often, what type is it?					.08
	Regular	50 (52.6)	21 (43.8)	29 (61.7)	
	Smart	45 (47.4)	27 (56.3)	18 (38.3)	

[a]FEW: female entertainment worker, SIM: subscriber identity module.

Table 4 presents data on privacy and mobile phone use. When asked to think about the phone they used most often, 39% reported that they often shared their phone; these FEWs most often shared the phone with work colleagues (43%); family (24%); husbands, boyfriends, or partners (22%); and friends (11%). When asked how comfortable they felt receiving text messages with private health information on their phones, 97% said that they felt comfortable. When asked how likely they were to respond to various types of private health questions, 79% were very likely to respond to a question about eating vegetables, 76% were very likely to respond to a question about smoking, 73% were very likely to respond to questions about condom use, and 87% were very likely to respond to questions about HIV.

Table 4. Privacy and short messaging service of study participants by age group (n=96)

Privacy and short messaging service variables		Total (n=96)	Younger FEWs[a] (27 and under) (n=48)	Older FEWs (Over 27) (n=47)	*P*
Thinking about the phone you use most often, do you share the phone with anyone else?		37 (39)	13 (27)	24 (50)	.02
Who do you share the phone with most often?					.78
	Work colleague	16 (43)	6 (46)	10 (42)	
	Family	9 (24)	2 (15)	7 (29)	
	Husband, boyfriend, or partner	8 (22)	3 (23)	5 (21)	
	Friends	4 (11)	2 (15)	2 (8)	
How comfortable do you feel receiving text messages with private health messages on the phone you most often use?					.56
	Comfortable	93 (97)	46 (96)	47 (98)	
	Not comfortable	3 (3)	2 (4)	1 (2)	
How likely are you to respond to health questions about vegetables?					.16
	Very likely	68 (71)	38 (79)	30 (63)	
	Somewhat likely	12 (13)	6 (13)	6 (13)	
	Not at all likely	6 (6)	2 (4)	4 (8)	
	Do not know	10 (10)	2 (4)	8 (17)	
How likely are you to respond to health questions about smoking?					.49
	Very likely	73 (76)	38 (79)	35 (73)	
	Somewhat likely	7 (7)	2 (4)	5 (10)	
	Not at all likely	16 (17)	8 (17)	8 (17)	
How likely are you to respond to health questions about condom use?					.14
	Very likely	70 (73)	31 (65)	39 (81)	
	Somewhat likely	5 (5)	2 (4)	3 (6)	
	Not at all likely	15 (16)	10 (21)	5 (10)	
	Do not know	6 (6)	5 (10)	1 (2)	
How likely are you to respond to health questions about HIV?					.10
	Very likely	83 (87)	38 (79)	45 (94)	
	Somewhat likely	3 (3)	3 (6)	0 (0)	
	Not at all likely	6 (6)	5 (10)	1 (2)	
	Do not know	4 (4)	2 (4)	2 (4)	

[a]FEW: female entertainment worker.

Younger FEWs were significantly more likely to work at sex entertainment venues and karaoke bars (*P*=.035) and to have ever sent a text message (*P*<.001); however, they were significantly less likely to share their phones with others (*P*=.021). Although not statistically significant at the *P*<.05 level, a greater number of younger FEWs owned smartphones than did older FEWs (*P*=.08).

Discussion

Our data suggest that mHealth interventions relying on texting may be a feasible way of reaching FEWs in Phnom Penh with health communication programming that aims to improve sexual and reproductive health literacy and access to prevention and care. Half of our respondents sent text messages on a daily basis, and younger FEWs were more likely to report daily texting

($P<.001$). Of those who sent text messages, 47% used Khmer script and 45% used Romanized Khmer. Most FEWs in this study reported feeling comfortable receiving private health messages, despite the fact that around half reported sharing their phone with work colleagues. Younger FEWs were less likely to share their phone with others. Smartphone use was surprisingly high, at 47%, and younger FEWs were more likely to own a smartphone as compared with older women.

The FEWs in our study had higher rates of smartphone ownership and texting in both Khmer script and Romanized Khmer than did those in a nationally representative study. These findings are supported by national data from a recent study on the use of mobile phones. Specifically, in this past study, conducted in 2014, which included a nationally representative sample of 2,066 Cambodians, 93% of respondents reported owning a mobile phone and 28% owned a smartphone, which was a 30% increase from 2013. Additionally, 68% of users knew how to send messages in Khmer script, which represents a 21% increase from 2013, while a quarter (26%) of the sample were able to send messages in Romanized Khmer [40].

These findings may inform future mHealth program designs. Given that more than half of the FEWs in this study did not have smartphones and that this proportion among older women was even less, app-based interventions may not reach an important and influential portion of the population. The delivery of information about where to find services, encouragement on how to protect oneself against HIV, and information on how to make contact with a peer counselor or call for a community-based finger-prick HIV test can all be done using simple text messages. However, an important limiting factor regarding the use of text messages is the low literacy levels in Cambodia, in both Romanized Khmer and Khmer script.

Smartphone use is predicted to increase further over the next decade. In a recent report by Ericsson, a mobile Internet company, usage trends suggest that smartphone subscriptions in Southeast Asia are set to grow approximately five-fold by 2019 [41]. Given the likely increase in smartphone use, the findings from this study suggest that smartphone apps may also be a powerful health tool in addition to text-based interventions.

The limitations of this study include the following. First, the small sample size requires us to be cautious in interpreting our results because of the limited ability to detect statistical significance. Second, we only included FEWs in Phnom Penh who have had some interaction with KHANA in our sample. The levels of mobile phone use and texting frequency reported in this study may therefore represent a more modern view than in other areas of Cambodia. Future studies should include a wider range of the national population, particularly those who have not yet been reached by the KHANA intervention programs.

Although this study had a small sample size, it provides important evidence for the mobile phone use patterns of a specific high-risk population within the context of rapidly increasing rates of mobile phone use in Cambodia. The findings from this study support the development of mHealth interventions targeting high-risk groups in urban areas of Cambodia.

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Conflicts of Interest

None declared.

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Perceptions of the Feasibility and Practicalities of Text Messaging-Based Infectious Disease Surveillance: A Questionnaire Survey

Linh Thuy Dang[1], BA; Nguyen Cong Vu[1], MPH, MD; Thiem Dinh Vu[2], MD, PhD; Spencer L James[3], MPH; Peter Katona[4], MD; Lindsay Katona[5], MPH; Joseph M Rosen[6], MD; Cuong Kieu Nguyen[1], PhD

[1]Institute of Population, Health and Development, Hanoi, Vietnam

[2]National Institute of Hygiene and Epidemiology, Hanoi, Vietnam

[3]Geisel School of Medicine, Dartmouth College, Hanover, NH, United States

[4]David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, United States

[5]College of Osteopathic Medicine, University of New England, Biddeford, ME, United States

[6]Thayer School of Engineering, Dartmouth College, Hanover, NH, United States

Corresponding Author:
Cuong Kieu Nguyen, PhD
Institute of Population, Health and Development
18 Lane 132, Hoa Bang Street
Hanoi, 122667
Vietnam
Phone: 84 437822388 ext 822
Fax: 84 437822399
Email: cuong.kieu.nguyen@phad.org

Abstract

Background: In Vietnam, infectious disease surveillance data are collected via a paper-based system through four government tiers leading to a large delay. Meanwhile, mobile phones are abundant and very popular in the country, and known to be a useful tool in health care worldwide. Therefore, there is a great potential for the development of a timely disease surveillance system through the use of mobile phone short message service (SMS) text messages.

Objective: This study aims to explore insights about the feasibility and practicalities of the utilization of SMS text messaging-based interventions in disease-reporting systems by identifying potential challenges and barriers in the text messaging process and looking at lessons learned.

Methods: An SMS text messaging-based disease tracking system was set up in Vietnam with patient reports texted by clinic staff. Two 6-month trials utilizing this disease tracking system were designed and implemented in two northern provinces of Vietnam to report two infectious diseases: diarrhea and influenza-like illness. A structured self-reported questionnaire was developed to measure the feasibility and practicalities of the system from the participants. On the completion of the second trial in 2013, participating health staff from 40 commune health centers in the two pilot provinces were asked to complete the survey (N=80).

Results: Most participants were female (61%, 49/80) and nearly half (44%, 35/80) were heads of a commune health center. Approximately two-thirds (63%, 50/80) of participants retained the basic structure of the SMS text message report and there was a strong influence (OR 28.2, 95% CI 5.3-151.2) of those people on the time they spent texting the information. The majority (88%, 70/80) felt the information conveyed in the SMS text message report was not difficult to understand. Most (86%, 69/80) believed that they could report all 28 infectious diseases asked for by the Ministry of Health by using SMS text messaging.

Conclusions: From a health center staff perspective, a disease-reporting system utilizing text messaging technology is easy to use and has great potential to be implemented and expanded nationwide. The survey showed positive perceptions and feedback from the participants and contributed to a promising practical solution to improve the surveillance system of infectious disease in Vietnam.

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KEYWORDS

SMS; SMS-based; infectious diseases; text messaging; surveillance; Vietnam

Introduction

Potential of Using Text Messaging in Health Care Systems

The use of mobile and wireless technologies to support the delivery of health care services has the potential to transform the face of global health service delivery [1]. In recent years, the number of developing countries that are using mobile technology to address health needs is growing [2]. This is seen especially in African countries; since 2014, a phone-based system for timely integrated disease surveillance and response in Rwanda has collected information on 23 infectious diseases from more than 50% of health facilities nationwide [3]. In 2007, Madagascar launched the first nationwide sentinel surveillance system for influenza-like illness (ILI) based on the use of mobile phones [4]. In Uganda, the feasibility and benefits of a short message service (SMS) text messaging-based reporting system have been demonstrated to help program managers monitor malaria in real time [5].

Mobile phones are becoming cheaper and increasingly accessible. By the end of 2013, there were 97 mobile phone subscriptions per 100 people worldwide. In Vietnam, the number of subscriptions was much higher than many other countries with 131 subscriptions per 100 people [6]. Given the wide coverage of mobile phone services and the low cost of SMS text messaging use in Vietnam, and the fact that the majority of community health centers in Vietnam do not yet use computers to provide their services, there is a great potential for the affordable provision of health services via mobile phones.

The Infectious Disease Surveillance System in Vietnam

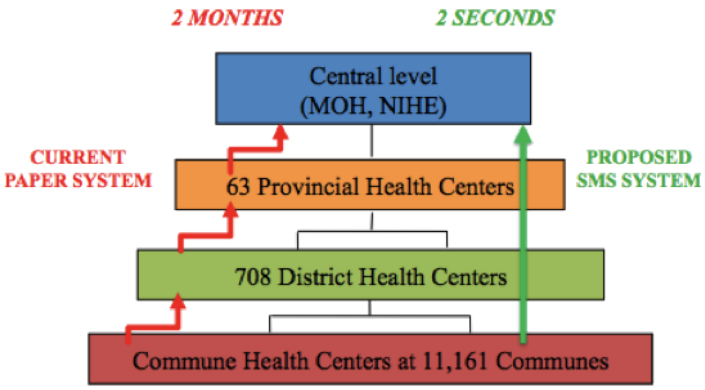
The Vietnamese health care system is hierarchically organized into four administrative levels: central, province, district, and commune. At the central level, the Ministry of Health (MOH), assisted by the National Institute of Hygiene and Epidemiology (NIHE) and other regional Pasteur Institutes [7], is the main national authority in the health sector and is responsible to formulate and implement national health policies and programs. At the provincial level, within each province there are Provincial Health Departments and Preventive Health Centers administered by the Provincial People's Committee. At the district level, the District People's Committee administers district health centers and district-level hospitals. A commune health center is a health facility at the lowest level, within each commune, and serves as a primary access point for public health and preventive care services [8,9]. Each commune health center typically provides services for an average of 5000 to 10,000 inhabitants in the commune and has only approximately five to six health care staff members, including one physician—usually the head of the commune health center—and four to five other health professionals, such as assistant physicians, nurses, midwives, and/or pharmacists. Due to the limited human resources for health service provision, one commune health center staff member would have to hold multiple duties and responsibilities; for example, a pharmacist or a nurse might be responsible for checking patients in and out in a paper logbook and reporting disease (a duty that a nurse is normally responsible for).

Infectious disease data in Vietnam are collected through a paper-based system in which data transfers through the four previously mentioned government tiers. Initiated at the commune health center, disease data (eg, cumulative incidence or mortality rates) are aggregated regularly from the patient logbook. The frequency of this commune-level data aggregation depends on the types of diseases, for example, monthly for ILI and diarrhea [10]. Information is then sent to higher administrative levels, to district health centers, then on to preventive health centers, ultimately arriving at NIHE for aggregation and analysis before being reported to the MOH [10]. As a result, through this reporting system, it usually takes 2 months or longer for a final report to reach the MOH (see the left-hand side of Figure 1).

This delay in disease reporting often defers the timely collection of the most recent disease data and contributes to longer government response times. Therefore, it has the potential to be catastrophic in emergency situations such as outbreaks. On the other hand, in addition to a heavy regular workload, the commune health center staff are required to report on a total of 28 infectious diseases [10]. In the effort to improve this, the MOH tested an Internet-based infectious disease monitoring and reporting system in seven provinces in 2012 [11] and officially launched this nationwide in 2014 [12]. However, the effectiveness of the current system remains limited for several reasons, including the fact that many commune health centers are not equipped with computers, have limited access to the Internet, and the system does not provide live trends of disease data.

In 2012, the Institute of Population, Health and Development, in collaboration with the NIHE, Dartmouth College, University of California, Los Angeles, and Columbia University, designed and piloted the use of text messaging for infectious disease surveillance in the public health care system in Vietnam [13,14]. Two 6-month trials were carried out in two northern provinces of Vietnam. A self-reported questionnaire survey was conducted at the end of the second trial in 2013 to evaluate and assess the feasibility and practicalities of the utilization of SMS text message-based disease-reporting system from the commune health center staff's perspective.

Figure 1. The flow of infectious disease information through the current paper-based reporting system (left-hand side) and the proposed SMS text message-based reporting system (right-hand side).



Methods

Study Settings

Two northern provinces of Vietnam—Hung Yen and Hoa Binh—were chosen to participate in the study. The first trial was carried out in a total of 20 communes from four districts: Hung Yen city and Yen My district in Hung Yen province, and Hoa Binh city and Ky Son district in Hoa Binh province, 5 communes each. The second trial was carried out in a total of 40 communes located as follows: 17 communes in Yen My district, Hung Yen province (a delta region); 13 communes in Cao Phong district, Hoa Binh province (a mountainous region); and 10 communes in Ky Son district, Hoa Binh province (a mountainous region).

In both trials, the commune health centers' heads selected and appointed two commune health center staff members from each of the participating communes to participate in the study.

Study Design

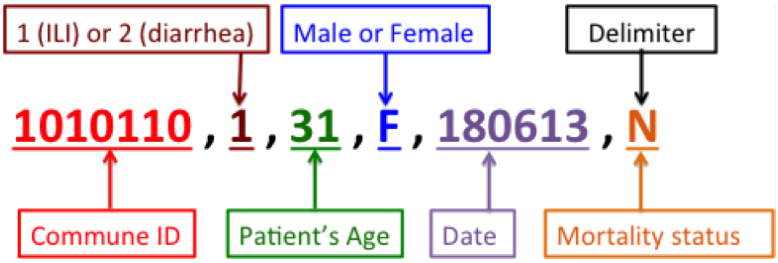
A central data repository server, monitored and managed by NIHE and the research team, was set up. The server was equipped with an SMS text message gateway to collect text messages through a designated cell phone number. In this study, the commune health center staff members were asked to text selective disease information for each record from the patient logbook in a structured but simple format to this cell phone number and make notes of successfully reported cases. Patients diagnosed to have either of the two commonly seen diseases in northern of Vietnam (diarrhea and ILI) were chosen to be reported. The disease data were then electronically collected and stored on the data server where data were summarized and analyzed further to generate the necessary reports. For the purposes of monitoring, the data were also made available on a data management website built on the server, which was securely accessible through the Internet. Only authorized personnel were able to access this data. The right-hand side of Figure 1 illustrates the flow of disease information performed by the proposed SMS text message-based reporting system: disease data were collected at the central level after just a few seconds and were available immediately for different government tiers through the previously mentioned website.

The two trials were implemented for a period of 6 months from July to December in both 2012 and 2013. Accuracy of the proposed text messaging reporting system was examined by aggregating disease data from SMS text message reports, summarizing, and comparing to data from the paper-based reports in the same period. An assessment survey was developed and all commune health center staff participating in the second trial in 2013 completed the survey. All related costs associated with the text messaging process in the study, including the cost of sending SMS text message reports, were covered by the project.

The Structure of the Text Message Report

The SMS text message was structured to contain a certain number of simple encoded disease information inputs separated by a designated delimiter. In the first trial, six chosen inputs were commune identification number (assigned uniquely by the research team), disease diagnosis (1 for ILI or 2 for diarrhea), patient's age, patient's gender, date of diagnosis, and mortality status. The delimiter was the comma character (see Figure 2). In the second trial, the same text messaging structure was used in the reported SMS text message, but with three different compositions tested in three mentioned districts. One district was asked to send six inputs: the first five were the same as in the previous trial plus ethnic group in lieu of mortality status for the last input. One district was asked to send in only three inputs: commune identification number, disease diagnosis, and date of diagnosis. The remaining district was asked to send in 11 inputs: commune identification number, disease diagnosis, patient's age, patient's gender, date of diagnosis, village, patient's occupation, patient's ethnic group, disease symptoms, treatment provided, and name of physician. In the second trial, a space character was used as a delimiter.

Figure 2. The structure of the SMS text message report in the first trial.



Training and Monitoring

Face-to-face training classes, focusing on SMS text message sending techniques and some typical mistakes, such as mistyping or duplicate reports, were provided to all the participants in preparation for the implementation of each of the trials. Two participating commune health center staff members from each commune health center, who were appointed and registered with the study by the commune health center's head, attended the training. Handouts and leaflets about the study were also provided to the commune health center staff members at the training.

To minimize mistyping, typos, or duplicate SMS text message reports, the data were monitored closely through the data management website by a project officer. Daily SMS text message reports were randomly checked and any mistyping or doubtful report was reported by phone to the corresponding commune health center staff member for double-checking, fixing, and resending if necessary. On-site monitoring trips were also organized every 3 months during the implementation of the project to some randomly chosen commune health centers, where the research team checked with the commune health center staff members to make sure the protocol of the project was followed precisely, for example, commune health center staff compliance with the SMS text message report sending instructions or consistency between the patient logbook and the SMS text message reports on any random date.

Survey Development and Data Collection

A structured self-reported questionnaire was developed to measure the feasibility and practicalities of the SMS text message-based reporting system. Information was collected including (1) general and demographic information of participants, such as gender, ethnicity, or position at the commune health center; (2) characteristics of SMS text message-based surveillance system, such as structure of SMS text message reports, time spent sending SMS text messages, or their thoughts about the system; (3) technical issues that arose during the texting process, what issues they met when sending messages, and how they dealt with the situation; (4) facilities at the commune health center, such as computer and Internet capabilities; and (5) participants' comments and suggestions.

The survey was conducted in January 2014 after the second trial ended. All 80 participating commune health center staff members from 40 communes were asked to anonymously complete the survey.

Statistical Analysis

Data entry was conducted using EpiData software [15] and data analysis was performed using Stata version 12.0 (StataCorp LP, College Station, TX, USA). Quantitative descriptive analysis, Pearson chi-square test, and multivariate logistic regression were used to examine different relationships and correlations from the survey data. A P value of <.05 was considered statistically significant.

Ethical Consideration

The activities in this study, which were reviewed and received MOH approval before the implementation, were considered to be part of the daily duty of the participating commune health center staff members. The study was designed to collect only patients' general information for statistical purposes. Access to the repository server, as well as the SMS text message reports and databases, were strictly controlled and only permitted authorized personnel. The questionnaire survey was developed to not contain any identifiable information from the participants and was conducted anonymously.

Results

Demographic and General Information

Most participants were female (61%, 49/80). Nearly half (44%, 35/80) were heads of commune health centers. One-third (34%, 27/80) of participants were ethnic minorities from mountainous areas in Cao Phong and Ky Son districts (see Table 1).

Overall, 29 of 80 participants (36%) took part in the first trial. Of these, 17 participants were from Ky Son district followed by 12 participants from Yen My district. Cao Phong district was new to the second trial. Only one participant (1%, 1/80) could not take part in the training for the second trial. Here, their colleagues successfully guided them on how to send the SMS text message report. The majority of participants (93%, 74/80) reported that they shared information on the project with other staff members. A mean 2.3 (SD 1.0) staff members in each of the 40 communes participated in the second trial (by district Cao Phong: mean 2.8, SD 0.8; Ky Son: mean 2.2, SD 1.7; Yen My: mean 2.0, SD 1.0).

When sending SMS text message reports, 73 of 80 participants (91%) used the Viettel network, whereas a small number of participants used other networks, such as Vinaphone (8%, 6/80) and Mobiphone (1%, 1/80).

Practicalities of the System

Overall, 50 of 80 participants (63%) retained the basis of the required structure and components of an SMS text message

report. This basic knowledge included three formatting requirements of an SMS text message report: the number of data inputs to be reported (3, 6, or 11), incidents per report (1), and the symbol used to separate the data inputs in the report (the delimiter, either a comma or a space). Cao Phong, a new district for the second trial, had the highest percentage of participants retaining the basis (88%, 23/26) among the three districts.

A detailed breakdown of the percentage of people retaining the basic structure of an SMS text message report into three formatting components is shown in Table 2. Regarding the number of data inputs to be reported, all participants in Cao Phong district (100%, 26/26), who were asked to send in six data inputs, recalled this number compared to Yen My (three inputs) with 94% (32/34). Participants in Ky Son district, who sent in the highest number of data inputs (11), had the lowest recall (75%, 15/20). When other components of the SMS text message format were examined (eg, incidents per message and the delimiter), Cao Phong still came out on top.

Table 1. Demographic information of participants.

Demographic information	Hung Yen (delta region), n (%)	Hoa Binh (mountainous region), n (%)		Overall, n (%) (N=80)
	Yen My (n=34)	Cao Phong (n=26)	Ky Son (n=20)	
Gender				
Male	12 (35)	12 (46)	7 (35)	31 (39)
Female	22 (65)	14 (54)	13 (65)	49 (61)
Ethnicity				
Kinh	34 (100)	12 (46)	7 (35)	53 (66)
Ethnic minority	0	14 (54)	13 (65)	27 (34)
Position in commune health center				
Head/physician	14 (41)	11 (42)	10 (50)	35 (44)
Nurse/assistant physician	14 (41)	3 (12)	3 (15)	20 (25)
Pharmacist	4 (12)	1 (4)	1 (5)	6 (7)
Other	2 (6)	11 (42)	6 (30)	19 (24)

Table 2. Percentage of participants retaining the three formatting structures of an SMS text message report: number of data inputs, incidents per report, and delimiter.

Basic structure of an SMS text message report	Yen My, n (%) (n=34)	Ky Son, n (%) (n=20)	Cao Phong, n (%) (n=26)	Overall, n (%) (N=80)
Number of data inputs	32 (94)	15 (75)	26 (100)	73 (91)
Incidents per SMS text message	22 (65)	13 (65)	23 (88)	58 (73)
Delimiter	22 (65)	19 (95)	26 (100)	67 (84)
Basic knowledge (all three formatting components above)	17 (50)	10 (50)	23 (88)	50 (63)

Overall, 88% (70/80) of participants felt that the information required to be reported was not difficult to text and 95% (76/80) of participants felt that no information should be removed from the messages, 89% (71/80) thought that no further information needed to be added, but a small number (5%, 4/80) suggested disease severity should be included. Regarding the adequacy of disease information to be reported per message, only a small number of participants thought the amount of information in the SMS text message was too much (6%, 5/80) or not enough (9%, 7/80).

Of the 80 participants, 55 (69%) agreed with the use of a space to separate each piece of information in an SMS text message, whereas some preferred using a period (18%, 14/80) or a comma (10%, 8/80) or no response (4%, 3/80). One-third (26/80) said that they usually sent disease cases after having the diagnosis confirmed, whereas 64% (51/80) reported they sent the SMS text message at the end of day.

The majority of participants (84%, 67/80) reported they did not spend much time sending messages, whereas 13 participants (16%, 13/80) felt that they needed more time. Of these, most (62%, 8/13) were from Yen My district, who needed to send in three data inputs, and from Ky Son (39%, 5/13), a district with 11 data inputs.

Regarding the time spent for performing the work, less than half of the participants (43%, 34/80) said they needed less than 1 minute to text a message, whereas some (11%, 9/80) said they needed more than 2 minutes (see Figure 3). The time spent sending the SMS text message was not significantly different between male and female participants (P=.15).

A multivariate logistic regression performed to study the influence of ethnicity, sex, and retaining the basic structure of an SMS text message report on the participants' report of taking less time to send SMS text message reports showed that there was a significant difference between different ethnic groups (OR 14.7, 95% CI 1.5-139.4) in which ethnic minority participants needed less time to text than Kinh participants (see Table 3). In Cao Phong district, all ethnic minority participants (100%, 14/14) needed less than 1 minute to send an SMS text message report compared with 92% (11/12) of Kinh participants, who needed 2 minutes or more. In Ky Son, three of five Kinh participants (60%) said they needed more than 2 minutes to send an SMS text message compared to three of 13 ethnic minority participants (23%). The rates for less than 1 minute were similar (Kinh: 20%, 1/5; ethnic minority: 23%, 3/13).

We also found a strong influence (OR 28.2, 95% CI 5.3-151.2) on the time spent sending an SMS text message for the participants who retained the SMS text message report's basic knowledge. A multivariate logistic regression model to study this influence on each of the components of the SMS text message report's basic structure found that although all three components had significant influence, the delimiter had the strongest impact on people who spent less than 2 minutes to send an SMS text message report (see Table 4).

Table 3. Multivariate logistic regression model on the participants' report of taking less time to send SMS text message reports.

Variables	OR (95% CI)	*P*
Basic structure of an SMS text message report		
Do not remember	1	
Remember	28.2 (5.3-151.2)	<.001
Sex		
Male	1	
Female	0.7 (0.1-3.6)	.67
Ethnicity		
Kinh	1	
Ethnic minority	14.7 (1.5-139.4)	.02

Table 4. Multivariate logistic regression model to study the influence of each component of the basic SMS text message report's structure on time spent to send an SMS text message report (less than 2 minutes to send).

Variables	OR (95% CI)	*P*
The number of data inputs		
Do not remember	1	
Remember	10.7 (1.4-79.9)	.02
Incidents per SMS text message		
Do not remember	1	
Remember	4.9 (1.3-19.4)	.02
Delimiter		
Do not remember	1	
Remember	13.2 (2.8-61.6)	.001

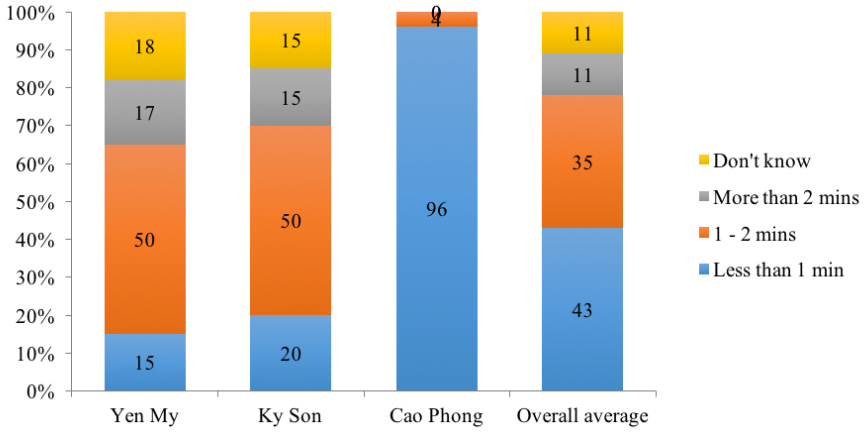
Information for all patients who visited the commune health center was recorded in a logbook. When sending an SMS text message report, commune health center staff were asked to make notes in the logbook to avoid duplicate reporting. A vast majority of participants (91%, 73/80) reported that they recorded reported cases in a logbook. Most participants (86%, 69/80) believed that they could report all 28 infectious diseases by using the SMS text message system. It was reported by the commune health center staff members that, on average, they saw a mean 6.9 (SD 3.2) patients per day (by district Cao Phong: mean 8.1, SD 2.7; Ky Son: mean 5.5, SD 3.3; Yen My: mean 6.9, SD 3.2).

When participants were asked about what ongoing support they would like to assist them with their work, half said they would like face-to-face refresher training (45%, 36/80) followed by handouts (39%, 31/80) and videos (19%, 15/80). When we looked at the two-group comparison, as shown in Table 5, ethnic minority participants (60%, 15/25) preferred refresher training compared to Kinh participants (43%, 19/44), who had a preference for posters and videos. This reflects the practicality of this type of work and the usefulness of having someone on the spot who can give hands-on guidance, answer questions, and solve problems quickly.

Table 5. Types of support requested by the participants.

Types of support	Kinh, n (%)	Ethnic minority, n (%)	Total, n (%)
Poster	10 (20)	1 (4)	11 (14)
Video	11 (22)	3 (11)	15 (19)
Handout	22 (44)	9 (33)	31 (39)
Refresher training	19 (38)	15 (56)	36 (45)
Other	10 (20)	2 (7.4)	12 (15)

Figure 3. Time spent sending an SMS text message report by district.



Technical Issues

Half of the participants (40/80) reported that sometimes they were not able to send the SMS text message to the server. Of these, 45% (18/40) said that this occurred rarely or sometimes (55%, 22/40). “No signal” was the biggest reason seen for this problem (65%, 26/40) followed by server issues (25%, 10/40) and unknown (10%, 4/40). Most of the “no signal” issues (65%, 17/26) were reported by health staff in Cao Phong district—a mountainous area. Where there were difficulties sending the SMS text message the first time, the majority (78%, 31/40) decided to send it again a later time. Less than half (40%, 16/40) decided to use another mobile phone to do this. Only a few (15%, 6/40) called the project team to ask about this issue.

Feasibility of the System

To assess the feasibility of the use of text messaging in a disease surveillance system, we performed multivariate logistic regression analysis to study the impact of the SMS text message report’s basic knowledge, the adequacy of disease information per SMS text message report, and the technical issues on the possibility of reporting all 28 infectious diseases by text messaging. The result showed that the SMS report’s basic knowledge alone highly influenced the possibility of reporting all 28 infectious diseases by text messaging (see Table 6). A deeper look at the effect of each of the components of the SMS text message report’s structure showed that although the incidents per SMS text message report and the delimiter had high influence (see Table 7), the number of data inputs per SMS text message report had no significant association (*P*=.30).

Table 6. Multivariate logistic regression model on the possibility of reporting all 28 diseases asked for by the MOH.

Variables	OR (95% CI)	*P*
Basic structure of an SMS text message report		
Do not remember	1	
Remember	8.6 (1.6-45.6)	.01
Disease information per SMS text message report		
Insufficient	1	
Sufficient	0.9 (0.1-9.4)	.91
Technical issues when sending an SMS text message		
No	1	
Yes	0.8 (0.2-3.7)	.82

Table 7. Multivariate logistic regression model to study the impact on the possibility of reporting all 28 diseases asked for by the MOH of different components of the SMS text message report.

Variables	OR (95% CI)	*P*
Incidents per SMS text message		
Do not remember	1	
Remember	6.4 (1.4-29.6)	.02
Delimiter		
Do not remember	1	
Remember	5.2 (1.1-24.6)	.04

Commune Health Center Internet Capabilities

The survey also investigated the computer and Internet capacity of the participating commune health centers. More than half (56%, 45/80) of commune health center staff reported that their health center was equipped with a computer; however, only 49% (22/45) had an Internet connection and, among those, most (82%, 18/22) said that their center had the budget to maintain it. Of the commune health centers that had a computer but no Internet access, 96% (22/23) were located in areas with the availability of broadband Internet services. Less than half (41%, 33/80) had the budget to cover the cost of this. For those commune health centers without a computer, Internet services were available for most of them (95%, 32/34), but only 26% (8/31) could afford the cost.

Input From Commune Health Center Staff

All participants were asked to provide their comments or suggestions to improve the SMS text message-based surveillance system. We received comments from 23 of 80 participants (29%). Of these, nine participants (11%) said that the system should be maintained and expanded to a larger scale, for example, provincewide or nationwide. Six participants (8%) wanted to have a feedback mechanism in the system to help them perform their work better. This included checking to see if there were any mistakes in the report or if their report had been sent successfully. In addition, five participants (6%) wanted to be provided computer and network facilities.

Discussion

Principal Results

The study showed that basic structure of an SMS text message report plays an important role in both the practicalities and feasibility of a pilot texting system. This includes a strong influence on the time spent to text a report and a high impact on the ability to send in all 28 infectious diseases as required by MOH using SMS text message reports. This also means education and training prior to commencement of the system, in combination with refresher training and other information, education, and communication materials, such as leaflets or posters, during the implementation are critical to the success of the project.

In terms of demographics, despite only two staff members per commune health center participating in the study, the sex ratio of the participants reflects the domination of female health staff working in health care facilities in Vietnam [16]. A mix of different health center staff positions, especially the commune health center's head, participating in the study may indicate the human resource limitation in health care in Vietnam, in which a staff usually has to hold multiple duties and responsibilities in their center.

One-third of participants in the study were ethnic minority who needed less time to text than Kinh participants did. This may demonstrate that participant's interest in a new and novel project could be a factor that influences the performance of their work. Ethnic minority participants, who live in remote and mountainous areas where health care services are limited, may be more interested and motivated about the use of health care technologies that might bring more benefit for them than Kinh participants. The outperformance of participants from Cao Phong district—a new district that had not been previously exposed to the project—may have also contributed to this point.

In terms of texting skills or the time spent to send an SMS text message, a strong relation between this and the SMS text message's structure basis showed that people who were fully engaged in the project were quicker and more effective in composing and texting messages. Therefore, skills in using a mobile phone along with concentration can be factors related to the time needed to send an SMS text message. That there was no significant difference in the time spent sending SMS text messages between male and female participants is intriguing. This finding does not reflect some recent studies on time spent by males and females in sending an SMS text message, where it was reported that women tended to spend less time than men [17,18], potentially due to women having smaller fingers enabling them to type faster and more easily [17].

In terms of technical issues, "no signal" came out on top among the reasons causing the inability to send an SMS text message. This is an ongoing challenge, especially for remote and mountainous areas in Vietnam, and ways of overcoming and mitigating these kinds of technical events to maintain commitment to the SMS text message reporting process include discussion with the mobile phone providers. However, our study showed that these texting technical issues do not affect the feasibility of the reporting system from the participant's perspective. Additionally, the study offered some creative ways invented by the participants to temporarily solve the issues, such as sending the message again or using another phone.

In terms of data accessibility and availability, the computer and Internet capacity of the commune health center would be useful for the participants to learn more about the project's information, to refresh their knowledge, and especially to create reports from the live data. However, computers and Internet are not fully equipped in all communes. This presents a challenge in terms of staff accessing data and transmitting reports electronically. The necessary funding support will be required to make all commune health centers fully operational.

Limitations

The survey did not cover inputs from the district, provincial, and national levels, which might provide more valuable information, such as on the administrative aspect of the project. Disease data aggregated from the pilot system and its comparison to a paper-based system and the statistics and problems of SMS text message reports, such as mistyping or duplicates, which would certainly contribute to a much stronger assessment of the system, was not discussed. In addition, the study was limited by its small sample size and includes a nonrandomized, uncontrolled single-arm study design that possibly precludes causal inference of the SMS text message-based report system to the outcomes.

Conclusions

Despite being a new disease-reporting system involving modern technology and knowledge, the SMS text message-based disease surveillance system demonstrated its ease of use and received positive feedback from participants. It is especially important that this work does not take too much time away from the health center staff's other duties. Although more in-depth studies might be needed to assess whether the information collected is sufficient for live reporting and outbreak prediction, the project showed its great potential to be implemented and expanded on a larger scale, such as provincewide or nationwide.

In addition to its perception and feasibility, the project provided valuable learning lessons, including regular refresher training for the commune health center staff, which is critical not only to enhance participants' engagement in the project, but also to improve the precision of reported data and to help solve technical problems. Well-prepared training, using a combination of lessons learned and experience gained from the previous trial, will also help a great deal in designing a more effective bidirectional instruction and training for the participants.

Some technical lessons were also learned from the two trials. First, improved software, which can recognize multiple delimiters, would eliminate the difficulties arising from the commune health center staff member's texting habits of using a comma (,) or period (.) to separate the reported piece of information. Second, an integrated feedback mechanism not only to address errors and concerns, but also to give disease information back to the health care worker will help in screening any mistake or typo in the reported SMS text message. Finally, a live disease trend map (or disease heat map) and a timely reporting system will help not only the high-level administration, such as MOH and NIHE, to make appropriate decisions and take the required actions in case of outbreak, but also the provincial, district, and commune staff in monitoring their work and generating reports when required.

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Conflicts of Interest

None declared.

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Abbreviations

ILI: influenza-like illness
MOH: Ministry of Health
NIHE: National Institute of Hygiene and Epidemiology
SMS: short message service

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Original Paper

Using a Mobile App to Promote Smoking Cessation in Hospitalized Patients

Joseph Finkelstein[1*], MD, PhD; Eun Me Cha[2*], MPH

[1]Columbia University, Department of Biomedical Informatics, New York, NY, United States

[2]Michael & Susan Dell Center for Healthy Living, The University of Texas School of Public Health, Austin, TX, United States

[*]all authors contributed equally

Corresponding Author:
Joseph Finkelstein, MD, PhD
Columbia University
Department of Biomedical Informatics
PH-20, Rm. 401A
622 W 168th St.
New York, NY, 10032
United States
Phone: 1 9174773909
Fax: 1 2123420663
Email: jf193@cumc.columbia.edu

Abstract

Background: The potential of interactive health education for preventive health applications has been widely demonstrated. However, use of mobile apps to promote smoking cessation in hospitalized patients has not been systematically assessed.

Objective: This study was conducted to assess the feasibility of using a mobile app for the hazards of smoking education delivered via touch screen tablets to hospitalized smokers.

Methods: Fifty-five consecutive hospitalized smokers were recruited. Patient sociodemographics and smoking history was collected at baseline. The impact of the mobile app was assessed by measuring cognitive and behavioral factors shown to promote smoking cessation before and after the mobile app use including hazards of smoking knowledge score (KS), smoking attitudes, and stages of change.

Results: After the mobile app use, mean KS increased from 27(3) to 31(3) (P<0.0001). Proportion of patients who felt they "cannot quit smoking" reduced from 36% (20/55) to 18% (10/55) (P<0.03). Overall, 13% (7/55) of patients moved toward a more advanced stage of change with the proportion of patients in the preparation stage increased from 40% (22/55) to 51% (28/55). Multivariate regression analysis demonstrated that knowledge gains and mobile app acceptance did not depend on age, gender, race, computer skills, income, or education level. The main factors affecting knowledge gain were initial knowledge level (P<0.02), employment status (P<0.05), and high app acceptance (P<0.01). Knowledge gain was the main predictor of more favorable attitudes toward the mobile app (odds ratio (OR)=4.8; 95% confidence interval (CI) (1.1, 20.0)). Attitudinal surveys and qualitative interviews identified high acceptance of the mobile app by hospitalized smokers. Over 92% (51/55) of the study participants recommended the app for use by other hospitalized smokers and 98% (54/55) of the patients were willing to use such an app in the future.

Conclusions: Our results suggest that a mobile app promoting smoking cessation is well accepted by hospitalized smokers. The app can be used for interactive patient education and counseling during hospital stays. Development and evaluation of mobile apps engaging patients in their care during hospital stays is warranted.

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KEYWORDS

mobile apps; patient engagement; hospital; smoking cessation; health literacy

Introduction

Smoking remains the most common cause of preventable mortality and morbidity in the United States [1] and the leading risk factor for global disease burden [2]. Tobacco consumption resulted in 435,000 deaths in the United States (18% of total US deaths) in 2000 [3]. Even after adjusting for multiple sociodemographic, behavioral, and health-related risk factors, overall estimate of deaths attributable to smoking in the United States was shown to be approximately 400,000 per year [4]. Although significant progress has been achieved in reducing smoking rates, one in five adults in the United States is a current smoker, with smoking prevalence remarkably higher among adults with lower educational attainment [5].

National surveys suggest continued need for patient education about smoking hazards [5]. While information on increased risk for cardiovascular disease and lung cancer has been widely publicized, many smokers still lack knowledge about cigarette smoking's relationship to other types of cancer, reproductive health problems, premature disability, and reduced quality of life [6]. Gender, age, racial, and socioeconomic disparities in knowledge and beliefs about smoking have been demonstrated, with males, older adults, non-Hispanic blacks, Hispanics, and those with lower incomes being significantly more likely to believe in myths such as reversal of smoking effects by exercise and vitamin intake [5]. While only 5% of graduate students smoke, 27% of adults with less than a high school diploma and 41% of those with a General Educational Development certificate are current smokers [1]. Recent studies demonstrated that lower knowledge of hazards of smoking is associated with higher tobacco use and higher tobacco-related morbidity and mortality [5]. These studies underscored the need for continued development and delivery of effective means to address disparities in tobacco-related knowledge.

Hospitalization offers an opportunity to provide smokers with advice, education, and counseling. Acute illness may increase a patient's motivation and has been described as a teachable moment that providers should not miss [7-9]. Hospital-initiated interventions for smoking cessation have been demonstrated to increase long-term quit rates [10] and even brief advice has been demonstrated to be of value when offered by providers [9,11]. However, systematic delivery of in-hospital, patient-tailored education and counseling on smoking continues to be far from routine [9,12] and only 18% of smokers overall abstain from smoking post hospitalization [13]. Language barriers, health literacy levels, lack of provider time, and limited resources are all factors that may contribute to this problem [14]. Multiple studies provided evidence that interactive health education programs can be instrumental in addressing these barriers [15-16].

Interactive health education programs delivered as mobile apps by touch screen tablets or smartphones have been demonstrated to increase knowledge, skills, and self-efficacy levels among patients with asthma, cancer, diabetes, congestive heart failure, chronic obstructive lung disease, and other conditions [17-18]. Such mobile apps, generally termed mHealth applications, may offer versatility and personalization, and may incorporate features that promote ease of use, use spoken and written language, use multiple languages, can be scripted at a level that addresses the needs of low literacy and numeracy learners, and may be viewed as often as needed by a patient [17-19]. Mobile apps supporting interactive education have the potential to greatly increase interest, because the learner actively participates in the learning process [20]. Limited computer experience and low-health literacy, which are more prevalent in individuals from low-socioeconomic strata, does not appear to impact their ability to use interactive health education programs effectively [21].

Recent studies have supported the use of mobile apps for smoking cessation [19-20,22,23]. Mobile apps for smoking cessation have been successfully implemented in a variety of settings and populations using multiple approaches and theoretical frameworks [24-26]. Comprehensive reviews of popular mobile apps for smoking cessation concluded that these apps can serve as powerful tools for smoking cessation in the future [27,28]. The review recommended that mobile apps for smoking cessation are developed in compliance with evidence-based principles and undergo rigorous evaluations [27,28]. A recent survey reported that the majority of health care providers embrace use of mobile apps for helping their patients quit smoking [29]. Despite wide introduction of mobile apps for health promotion to the general public, the use of mobile apps aimed at promoting smoking cessation in hospitalized patients has not been studied yet systematically [30].

In a previous study, we assessed the feasibility of promoting smoking cessation in the outpatient setting using an interactive health education program [31]. After completion of the "Hazards of Smoking Educational Program" delivered via a touch screen tablet, low-literacy patients with minimal computer skills exhibited a significant increase in knowledge levels about hazards of smoking and reported ease of system use [31]. In the current study, we sought to elucidate feasibility and potential impact of a mobile app to educate smokers in the hospital setting. Our objectives were to (1) describe the sociobehavioral characteristics of hospitalized smokers to inform future mobile app development for this population, (2) assess impact of the mobile app on smokers' knowledge levels and behavioral factors associated with smoking cessation, (3) identify factors affecting users' knowledge gain, (4) identify factors affecting patient acceptance of the mobile app in a hospital setting.

Methods

Participants

We conducted a prospective study of active smokers consecutively admitted to two medicine units at two large urban academic teaching hospitals. Fifty-five consecutive adults aged 18 years or older hospitalized for any reason and who were active smokers and agreed to participate, were enrolled into the study. The study protocol was approved by the institutional review board.

Mobile App

The mobile app employed in this study was based on the COmputer-assisted EDucation system (CO-ED), which was previously described [31-35]. Briefly, CO-ED is designed to deliver interactive health education via multiple health communication channels [32,33] and was successfully used for patient education on a variety of health-related topics including asthma [34], diabetes [35], hypertension [36], depression [37], multiple sclerosis [38], ileostomy [39], smoking cessation [40], and Tai Chi [41]. The system consists of three components: knowledge repository containing educational content in a relational database format, teaching engine delivering educational content in concordance with major constructs of adult learning theories, and user interface supporting content delivery via multiple platforms including desktops, touch screen tablets, smartphones, gaming appliances (Wii and Xbox), and interactive voice response [33]. The CO-ED system is guided by principles of adult learning [42] and instructional technology foundations [43] using constructs from the Information Processing Theory [44], Constructivist Theory [45], Cognitive Flexibility Theory [46], Subsumption Theory [47], Drive Reduction Theory [48], and Cognitive Load Theory [49]. Applications of specific constructs from these theories in the CO-ED system were described in detail previously [33,50].

Previous studies emphasized importance of usability factors for successful acceptance of computer-assisted education especially in older adults and individuals with limited computer experience [35-39,51]. In this study, hospitalized patients were provided a touch screen tablet with a mobile app delivering computer-assisted education on the hazards of smoking. A touch screen tablet was chosen because of larger form factor as compared with a smartphone and because some of the hospitalized patients didn't use smartphones. The educational curriculum on hazards of smoking is written at the 5thgrade level and based on a previously developed curriculum that has been adapted for use in the CO-ED system [31]. Brief educational statements about the effects of smoking and the feasibility of quitting are presented, each followed by a multiple choice question about the material. A voice-over option is available for people with functional illiteracy. The curriculum was comprised of five sections: (1) Is cigarette smoking dangerous? (2) How does smoking cause cancer? (3) How does smoking cause heart disease, stroke, and blocked arteries? (4) How does smoking cause lung disease? (5) Common questions about smoking. Overall, the curriculum reflected key content areas promulgated by recent recommendations including the dangers and effects of cigarette smoking as well as information on how to quit [1,51].

Intervention

As this project was undertaken in preparation to wide introduction of tablet-based education for hospitalized patients, patient enrollment procedures were made as close to routine hospital workflow as possible. Hospital unit census was reviewed by a unit nurse on a daily basis to identify hospitalized smokers. Eligible participants were approached by a unit nurse and asked if they are interested to take part in the study. Interested patients were consented by study's research assistant. After obtaining informed consent, the research assistant provided each patient with a set of questionnaires to fill out and then provided a touch screen tablet with which the patient accessed a self-paced interactive education app on hazards of smoking. Patients spent up to 45 minutes using the mobile app independently without research assistant or nurse present. At the end of the 45-minute period, patients were approached by a research assistant again and asked to fill out a post-education survey. A 15 to 20 minute semistructured interview was also conducted at the end of each session so that patients could offer feedback on the feasibility of using the mobile app and ways to improve it.

Data Collection and Study Instruments

Prior to system use, participants completed a set of questionnaires with questions about demographics, prior experience with mobile devices, and the Fagerstrom Test for Nicotine Dependence (FTND) [52]. Though the primary objective of our intervention was increase in hazards of smoking knowledge, we also were interested in elucidating the extent of impact of potential knowledge change on major behavioral constructs that are frequently used to explain smoking cessation behavior. Thus, cognitive and behavioral factors known to be associated with smoking cessation were collected to ascertain impact of the mobile app. A Knowledge Score (KS) questionnaire, Process of Smoking Cessation survey (to assess stages of change per Transtheoretical Model (TTM)), Smoking Self-Efficacy questionnaire, and Decisional Balance Scale were completed by participants pre- and post-mobile app use. To assess each participant's experience with and opinions about the mobile app, an attitudinal survey and semistructured interview were administered to each of the study participants after using the mHealth education app.

The KS questionnaire is composed of 34 true or false questions asking basic information about smoking and negative impact of smoking on health. Examples of questions include: "Smoking during pregnancy is linked with a greater chance of miscarriage" and "Smoking only affects the lungs." An identical questionnaire was completed before and after using the system. A perfect KS on the test is 34. The reliability of the KS scale assessed by the Cronbach's alpha in our studies including the current one has been 0.75 and higher [31,50].

The Process of Smoking Cessation survey measures four different stages of quitting based on the TTM of change [53]. In the precontemplation stage, the smoker is not seriously thinking about changing the smoking behavior. In the contemplation stage, the smoker is more aware of the health consequences of smoking and starts thinking about quitting. In the preparation stage, the smoker has made a decision to stop smoking and is starting to take small steps toward cessation. In the action stage, a smoker believes that s/he has the ability to quit smoking and is actively involved in changing their smoking behavior. In the maintenance stage a person has changed and is now trying to maintain the change [53,54].

The Smoking Self-Efficacy questionnaire [55] is composed of 20 questions assessing confidence in ability to avoid smoking. It is divided into three sections reflecting three relapse situations: positive affect/social situations, negative affect situations, and

habitual/craving situations with the highest section score of 30, 30, and 25, respectively. Three sections inquire about social factors, negative emotional states, and physiological factors like cravings and urges, which might trigger smoking. Higher scores are seen among those smokers who are more tempted to smoke.

The Decisional Balance Scale [56] is designed to assess and predict smoking behavior. It consists of 20 scales and is divided into two sections with 10 questions each. The Pros scale contains items representing the pleasure, tension reduction, self-image, and habit factors identified as the basic reason for smoking. The Cons scale items represent the health examples, aesthetics, and mastery considerations associated with motives for quitting. The score ranges for both Pros and Cons between 10 and 50. The comparison of Pros and Cons provides an insight on individuals' status regarding their decision to continue or discontinue smoking [56].

The Attitudinal Survey assesses patients' acceptance of the mobile computer-assisted education system and their perceptions of usability, content clarity, and usefulness of the system. The survey, which is composed of 18 items, was developed based on a literature review and critical feedback from experts in the field. The maximum survey score is 72. This survey has been used and validated in our previous studies [31-34].

The semistructured interview conducted at the end of the study explored participant opinions on educational content and the app interface. Participants were also asked to highlight mobile app benefits and drawbacks and to suggest areas for improvement. A qualitative thematic analysis was conducted using framework approach [57].

Data Analysis

Data were analyzed using SAS statistical software version 9.2 [58]. We calculated difference in knowledge test scores for pre- and post-system use for each participant along with a composite score for the attitudinal survey. To check for statistical significance we used paired *t* -tests and two sample *t* -tests, as applicable, for continuous variables. We used two-tailed tests with a .05 significance level. To assess impact of variables such as race, age, and computer skills on knowledge gain from the mobile app, a multivariate linear regression model was used with difference in KS (DKS) before and after the mobile app use as dependent variable and age, race, gender, computer skills, educational level, and baseline KS as covariates. Pre/post proportions were compared using two-sided chi-square test. To check for the potential impact of various variables on participants' attitudes toward using the mobile app, a multivariate linear regression model was used with the composite score on the attitudinal survey as the dependent variable and age, race, gender, computer skills, educational level, and KS difference as covariates. Mean (M) and standard deviation (SD) for continuous variables are reported in the following notation: M(SD).

Qualitative interviews were transcribed verbatim. The interview transcripts were independently analyzed by two researchers. A coding scheme was used to reflect themes that emerged from the data following a framework approach in analysis of qualitative data [57,59]. A comprehensive search was conducted for expressions indicating information types and the context of use, and possible problems when looking for or using information [57]. Adapted from a taxonomy that resulted from similar research [60], the information types were coded into (1) interface-specific, (2) content-specific, and (3) process-specific. Differences in coding by the two independent researchers were reviewed and reconciled until agreement was reached.

Results

Sociobehavioral Characteristics of Hospitalized Smokers

Participants' demographic and socioeconomic status is detailed in Table 1. Overall, 55 eligible patients consented and participated in this study which constituted three-quarters of initially approached adult hospitalized smokers. Main reasons for refusal to consent were being too tired, too sick, or being distracted by upcoming tests or procedures. The mean age of study participants was 46.9(11.36)-years old ranging from 18 to 69 years.

Table 1. Participant sociodemographic characteristics.

Sociodemographic characteristics	N=55	%
Gender		
Male	30	55
Female	25	45
Current relationship status		
Married/Common-law/Partner	15	27
Single/separated/divorced/widowed	40	73
Education		
<12 years	18	33
12 years	24	44
>12 years	13	24
What is your level of computer skills?		
None/basic	31	56
Good/advanced	24	44
Current employment status		
Employed	12	22
Unemployed	43	78
What is your overall household income for the last year?		
<20K	19	35
20K-40K	12	22
>40K	9	16
Prefer not to disclose	15	27
Race		
Caucasian	23	42
African American	30	55
Other	2	4

Women constituted 45.5% (25/55) of enrolled smokers, 55% (30/55) were African Americans, and 42% (23/55) were Caucasians. Approximately 20% (11/55) of the study participants had a full-time employment, 33% (18/55) did not have high school diploma, and 44% (24/55) completed high school. Thirty-five percent (19/55) reported a low income household (<US$20,000 annual income per household). Fifty-six percent (31/55) had only a basic level of computer skills or no computer skills, and 53% (29/55) reported using a computer no more than once per week. Based on the patient chart review, 76% (42/55) of the study subjects were hospitalized for emergency treatment, 14% (8/55) for complex diagnostic procedures, and the rest for surgery or other treatment. Alcohol and drug abuse was the most frequent comorbid condition (20/55, 36%), followed by depression or other emotional problems (19/55, 34%), hypertension (15/55, 27%), heart disease and stroke (12/55, 22%), chronic obstructive pulmonary disease and asthma (12/55, 22%), diabetes (6/55, 11%), and cancer (5/55, 9%).

Smoking history of the study participants is summarized in Table 2. The subjects smoked an average of 13.6(9.1) cigarettes per day for 26.6(13.7) years. The participants started smoking at 18 years of age on average. Twenty-seven percent (15/55) of participants had never attempted to stop smoking, while 65% (36/55) had made at least one successful attempt that lasted for a full month or longer. Forty percent (22/55) of the study participants reported that they were ready to quit within 30 days and have made at least one 24-hour quit attempt during the past year. Another 43% (24/55) were thinking of quitting within the next 6 months. According to the findings from the FTND, half of the study participants typically smoked a cigarette within 5 minutes of waking, and 67% (37/55) answered that the first cigarette was the one they most hate to give up during the day. The mean FTND score for the participants was 4.7(2.8). FTND score of 5 or more indicates significant dependence, while a score of 4 or less shows a low to moderate degree of dependence. Fifty-six percent of study subjects (31/55) had FTND score above 5 demonstrating significant smoking dependence.

Table 2. Participant smoking history.

Smoking history characteristics (Mean (SD))	N=55	%
How many cigarettes a day do you smoke in average?	13.6 (9.1)	
How many days have you been already in the hospital?	3.3 (2.1)	
How many days have you been smoking while in the hospital?		
0 (ie, no smoking in the hospital)	44	80
1-2	8	15
3	3	5
How many persons in your household smoke?	2.0 (1.5)	
How many years have you smoked cigarettes regularly?	26.6 (13.7)	
How old were you when you started smoking cigarettes?	18.2 (10.4)	
How many times have you SERIOUSLY tried to stop smoking?	2.4 (2.5)	
What is longest number of months you have not smoked, not even a puff?		
Never stopped smoking	15	27
Less than a month	4	7
At least one month	36	65
In the past year, have you stopped smoking cigarettes for at least one day (24-hours)?		
No	10	18
Yes	45	82
How seriously would you like to give up smoking altogether?		
Not at all	4	7
Not very seriously	6	11
Fairly seriously	14	25
Very seriously	31	56

Impact of the Mobile App on Smokers' Knowledge Levels and Behavioral Factors

Table 3 summarizes effect of the mobile app on cognitive and behavioral factors associated with smoking cessation behavior. The use of the mobile app resulted in increase of hazards of smoking knowledge assessed by the KS questionnaire from 27.4 (2.6) to 30.5(3.1). This increase was statistically significant (paired *t* -test; $P<0.0001$). Based on the subjects' answers to the baseline KS questionnaire, participants already had good knowledge at baseline about addictive properties of tobacco and the increased risk for stroke, heart disease, lung cancer, and other respiratory tract cancers among smokers. They, however, lacked knowledge about other systemic effects of tobacco use such as increased risk for leukemia, colon cancer, and cervical cancer.

Table 3. Smoking knowledge and attitudes before and after the mobile app use.

Cognitive and behavioral factors of smoking cessation	Pretest	Posttest	*t* -test
Knowledge Score Questionnaire (mean±(SD[a]))	27.4 (2.6)	30.5 (3.1)	0.0001[b]
Attitudes toward smoking	**%**	**%**	χ^2 ***(P)***
I cannot quit smoking	36	18	4.6 (0.03)[b]
I have no desire to quit smoking	18	13	0.6 (0.43)
I would lose a lot in my life if I quit smoking	15	11	0.3 (0.57)
Health risks of smoking are exaggerated	20	11	1.7 (0.19)
If I continue to smoke, my risk of dying from smoking-related disease is significantly higher comparing with an average nonsmoker	89	95	1.1 (0.30)
Self-efficacy/temptation factors [c]	**Mean±(SD)**	**Mean±(SD)**	***t*** **-test**
Positive Affect/Social Situations	21.3 (5.9)	20.8 (6.3)	0.64
Negative Affect Situations	24.5 (5.0)	23.4 (5.7)	0.26
Habitual/Craving Situations	16.3 (4.9)	15.9 (5.2)	0.69

[a]SD: standard deviation.

[b]Pre/post difference is statistically significant.

[c]Higher the score, more tempted to smoke.

The mean baseline KS was significantly lower among African Americans than among Caucasians (African American KS = 26.7(2.8), range=19.0-31.0; Caucasian KS = 28.4(2.1), range=25.0-33.0; *P* value=.02). Both African American and Caucasian participants had higher average KS after using the mobile app (African American KS = 29.8(3.9), range= 14.0-34.0; Caucasian KS= 31.3(3.4), range=29.0-34.0; *P* value = .06). Thus, after using the mobile app, the disparity in the smoking knowledge score between African American and Caucasian subjects became insignificant.

Figure 1 depicts a scatterplot of post-KS against pre-KS scores by race. All points above the diagonal line represent gains in knowledge. All study participants except one African American and one Caucasian participant achieved a higher KS post using the mobile app. Both of these patients were recently admitted to the unit and their condition was not fully stabilized. All patients with baseline KS < 25 were African American, and all but one achieved knowledge gains following the mobile app use.

Figure 2 depicts distribution of study participants across the TTM stages of change pre- and post-mobile app use, based on the Process of Smoking Cessation survey. Overall, 13% (7/55) of patients moved toward more advanced stage of change. The percentage of participants in the precontemplation and contemplation stages decreased after mobile app use with a corresponding 11% increase in percentage of patients reaching the preparation stages. Proportion of patients in precontemplation stage decreased from 16% (9/55) to 14% (8/55) whereas the proportion of patients in the preparation stage increased from 40% (22/55) to 51% (28/55).

The mobile app positively affected patient attitudes regarding smoking cessation (Table 3). At the baseline, 36% (20/55) of patients felt they “cannot quit smoking.” After computer-assisted education, the proportion of patients who felt they “cannot quit smoking” reduced to 18% (10/55). Two-sided chi-square test showed that this change was statistically significant (*P*<.03). Other attitudes related to desire to quit smoking, feeling a loss after quitting smoking, believing that risks of smoking are exaggerated, and assessing risks of dying from smoking demonstrated improvements in a positive direction (Table 4). The Smoking Self-Efficacy Survey showed a decrease in mean scores from the pretest to the posttest demonstrating perceived reduction in temptation to smoke (Table 3) after the tablet use; however, this change did not reach statistical significance. The Decisional Balance Scale showed modest improvements which did not reach statistical significance.

Table 4. Attitudinal survey (N=55)

Question	Option[a](%)			
	1	2	3	4
1. How complicated was it to use the computer?	2	4	6	88
2. Did you have any difficulty moving from one screen to another?	90	10	0	0
3. How difficult was it to use the keyboard/mouse?	2	0	10	88
4. Did you have any difficulty reading text from the computer screen?	94	6	0	0
5. Was the size of the text presented on the screen sufficient?	94	4	0	2
6. Did you like the colors used on the computer screen?	82	14	4	0
7. Did you like the audio/visual content provided by the computer?	82	14	4	0
8. Did you get all the necessary information about using the computer during initial practice session?	88	12	0	0
9. Did you come across any unknown words which were not explained by the computer?	4	4	14	78
10. How difficult were the sentences used in the educational materials?	2	2	14	82
11. How much new information did you get using the computer?	47	41	8	4
12. Did you get any feedback from the computer about your learning progress?	59	31	8	2
13. How frequently did you find the information confusing?	6	10	37	47
14. How frequently did you find educational contents difficult to understand?	2	12	20	65
15. Did you have to wait for new information to come up on the screen?	2	6	14	78
16. Would you like to use this type of computer education in the future?	76	23	0	2
17. Would you advise other patients to use computer education?	92	6	2	0
18. Overall how would you grade this learning experience?	0	8	16	76

[a]The following options were used for the questions above (in the ascending order):
#1: Very complicated, Moderately complicated, Slightly complicated, Not complicated at all
#2, #4: Not at all, Very rarely, Frequently, All the time
#3, #10: Very difficult, Moderately difficult, Slightly difficult, Not difficult at all
#5: Fully sufficient, Sufficient almost all the time, Sufficient some of the time, Not sufficient at all
#6, #7: Certainly yes, To a large extent, To some extent, No
#8: All information, Almost all information, Partial information, Very limited information
#9: Very significant amount, Considerable, A few, None
#11: Very significant amount, Considerable, Little, Very little
#12, #15: All the time, Occasionally, Very rarely, Never
#13, #14: Very frequently, Occasionally, Very rarely, Never
#16, #17: Certainly yes, Maybe, Unlikely, No
#18: Needs serious improvement, Satisfactory, Good, Excellent

Figure 1. Scatterplot of post-KS against pre-KS values stratified by race (circles: African Americans, squares: American Indians/Alaska Natives, stars: Caucasians).

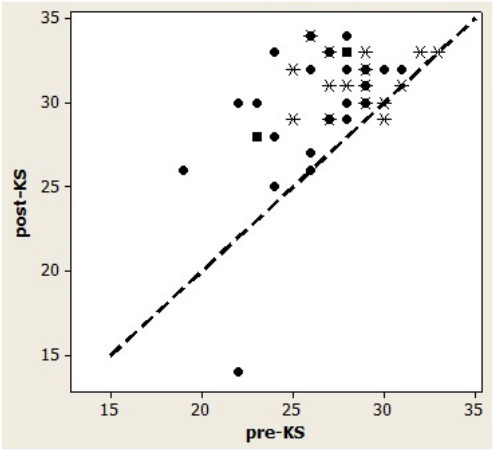
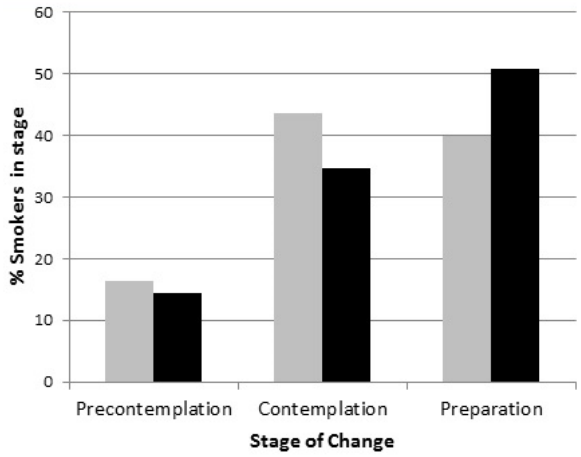


Figure 2. Distribution of stages of change before and after the mobile app use (gray bars: before the app use, black bars: after the app use; see detailed description in the text).



Factors Affecting Users' Knowledge Gain

To ascertain what factors affected successful improvement in hazards of smoking knowledge after using the mobile app, a multivariate linear regression analysis was performed with pre/post DKS as dependent variable, and baseline KS, age, gender, race, education level, working status, app acceptance, and computer skills level as independent covariates. The analysis demonstrated significant relationship between baseline KS and subsequent knowledge gain after using the mobile app, with lower baseline knowledge scores predicting a higher knowledge gain after using the app (P<.02). Other significant factors affecting knowledge gain were working status and app acceptance. Being fully employed (P<.05) and having high acceptance of the app (P<.01) were associated with higher knowledge gain from using the app. No significant influence on knowledge gain was found for other independent variables including age, gender, race, educational status, and computer skills.

Factors Affecting Patient Acceptance of the Mobile App in a Hospital Setting

Table 4 details results from the attitudinal survey administered to each participant after their use of the mobile app. Overall scores on attitudinal survey ranged from 53 to 72 with mean score of 67(4). Eighty-eight percent (48/55) of the participants reported that the mobile app was not complicated at all, 96% (53/55) liked the colors used on the screen and the audio/visual content, 88% (48/55) reported obtaining considerable amount of new information, 92% (51/55) answered that they would recommend other patients to use such an app, and 98% (54/55) of the patients were willing to use such an app in the future.

In order to identify factors affecting patient acceptance of the mHealth education app, a multivariate logistic regression analysis was performed with attitudinal survey score as the dependent variable, and age, gender, race, educational status, computer skills, income, and DKS, as independent covariates. For this analysis, attitudinal survey score and DKS were dichotomized to high/low acceptance and high/low knowledge

gain levels correspondingly based on their distribution. The main factor significantly affecting acceptance of the mHealth education app was knowledge gain (DKS). People with higher knowledge gain after using the app were 4.8 times more likely to exhibit more favorable attitudes toward the mobile app (odds ratio (OR)=4.8; 95% confidence interval (CI) (1.1, 20.0)). Other covariates such as age, gender, race, income, education, and computer skills did not appear to significantly affect the mobile app acceptance by the hospitalized smokers.

During the semistructured interviews, participants were asked to share their experiences and provide suggestions in three areas related to the mobile app: content, interface, and value of the program. Table 5 highlights common themes and key quotes from the semistructured interviews. The participants stated that they favored the interactive computer-assisted learning over other methods like books, magazines, videos, compact discs, or talking to health care providers while in the hospital. Ninety-six percent (53/55) said that the interface design was easy and fun to use, 88% (48/55) stated that they learned significant amount of new information, and 92% (51/55) recommended this type of computer-assisted education for other hospitalized patients. Ease of operation was high, with 85% (47/55) of the participants stating that they did not need help while using the system. Most participants mentioned that the multiple choice questions helped to reinforce the material, however, one participant commented that open-ended questions might be helpful too. Of great interest is that the majority of the participants stated that the app helped them consider quitting smoking. As one of the participant stated, "This is a good program to change people's minds who smoke. I start thinking about quitting now. This program made me want to quit smoking."

Table 5. Examples of qualitative feedback on the mobile app.

Key quotes from the semi-structured interviews		
Content		
Information value	**Comprehension problems**	**Improvement suggestions**
It gives information you need; I've learned a lot; it was very educational to me. I thought I knew it all, but I didn't know a lot.	I feel I do not know enough, I am not good enough to understand; a couple of questions were little confusing.	I would like more of the scientific info messages like the number of poisonous elements in a cigarette; include more scary disease related subjects, to show – this is what you are doing to yourself; simpler words, smaller sentences; add video clips; a little animated character like GEICO lizard; more animation would be better; make it into the video game. A super hero stops people on streets and saves them from smoking. Crossword puzzle – all bad words about smoking cigarettes.
Interface		
Problems	**Ease of use**	**Improvement suggestions**
There was slight pause (delay) between the message and the quiz. It made me skip to the quiz directly; sometimes I had to click couple of times to move to next screen; I hit a wrong button once but I caught up.	I didn't have any difficulty; just click.	Something other than clapping: for example, Ta-da sound I would make it simple. Simple is the best; may be male voice; may be music on the background; bigger screen; headphones; I would like to be able to go back to the content (message) if I am not sure. Addition of 'Back' and 'Forward' button would be helpful.
Program process		
Attitudes toward computer	**Program usefulness**	**Program effectiveness**
I don't like flipping pages. Paper is cumbersome. Computer is self-contained. I have more control with computer. Quicker and better with computer than learning from brochures; I like Hands On, an interactive part, the computer was better – I would NOT read hand out brochure; computer is much better – you got to see images. Radio is just read, TV got images, but here you have it all.	I think people need to do this program to learn about smoking. I think more people need to do this program to learn what they are breathing into their bodies; kids are using computers. Getting to kids through computer will get the message of hazards of smoking across to them. Get it to schools.	I am going to quit now. I will not pick up a cigarette ever in my life; This is a good program to change people's minds who smoke. I start thinking about quitting now. This program made me want to quit smoking.

Discussion

Principal Findings

In this study we demonstrated that delivery of a 45-minute interactive education via a mobile app on hazards of smoking for hospitalized smokers is feasible and associated with a statistically significant increase in hazards of smoking knowledge levels as well as positive changes in patient smoking attitudes, self-efficacy, and readiness for quitting based on stages of the TTM. These positive effects were demonstrated regardless of gender, race, educational level, or computer skills. Significant determinants of successful use and acceptance of the mobile app by hospitalized users were identified.

The study provided important insight on sociobehavioral characteristics of hospitalized smokers understanding of which is essential in developing mobile apps for hospitalized smokers. Majority of them had a long history of tobacco consumption with FTND scores indicating high levels of nicotine dependence. Despite a smoking ban at the hospital premises, 20% (11/55) of the participants indicated that they smoked during their hospital stay. Over three-quarters of these patients were hospitalized for emergency treatment with alcohol and drug abuse being the most frequent comorbid condition (20/55, 36%), followed by depression or other emotional problems (19/55, 34%). Due to high level of distress at admission, the patients were offered mobile app only at the second or third day of their hospital stay. The mean number of smokers in the household of hospitalized smokers was 2.0(1.5). Thus, education about hazards of secondary smoking as well as involvement of household members in a smoking cessation program is necessary for these patients. Despite high levels of nicotine addiction, over 80% of the patients tried to stop smoking in the past and majority stated that they would like to give up smoking in the future. The distribution of stages of change in the hospitalized smokers and in general population differed remarkably. In our study initial distribution of smokers in precontemplation, contemplation and preparation stages was 16%, 44%, and 40% whereas in general population this distribution was reported to be 37%, 47%, and 16%, correspondingly [61]. High proportion of people in contemplation and preparation among hospitalized smokers coupled with inability to achieve maintenance in smoking cessation in the past underscores high importance of assistance in smoking cessation that should be provided to these patients during their hospital stays. Given that the mobile app positively affected cognitive and behavioral factors associated with smoking cessation, it can be used as an integral component of a hospital-based smoking cessation program.

Most of our study participants were African Americans, were unemployed, and had low-education and low-income levels. The majority of patients had very limited computer education. At baseline, Caucasians, employed patients, and those with higher-education level demonstrated better knowledge about hazards of smoking but all groups appeared to benefit from this intervention regardless of their background. Differences in baseline knowledge were significant between African Americans and Caucasians; however, after using the mobile app the knowledge scores in both groups increased, and the difference in the mean KS between these two groups became insignificant. Thus, the mobile app helped to decrease racial disparity in health literacy as it pertains to the hazards of smoking knowledge.

The mobile app used in this study aimed to increase patients' knowledge levels about hazards of smoking and was successful in doing that regardless of race, gender, computer skills, or educational level. The mobile app delivered a very simple interactive curriculum that can meet the educational needs of patients who are able to read at a fifth grade level. It is likely that the consistently positive impact of the mobile app on knowledge gains among the study participants is related to the app's interface features, such as specifically developed content for low literacy users, one message per screen, question and answer format, voice-over option to address functional illiteracy, and use of illustrations as content anchors. Based on the regression analysis, the main predictor of knowledge gain was the baseline knowledge score. This is anticipated because with higher baseline scores, there is not as much room for knowledge gains resulting in a ceiling effect.

In regard to hospitalized smokers' readiness for change, our results are consistent with earlier studies showing that the majority of hospitalized smokers are in the contemplation and preparation stages. In a recent study, among hospitalized patients, Katz et al [62] reported that 61% of their study participants were ready to quit immediately; another study among hospitalized patients with cardiac diagnosis showed that three quarters were thinking of quitting within 6 months with approximately half of those ready to set a quit date [13]. In our study, participants were admitted for a variety of reasons, often less life threatening than an acute cardiac condition and many unrelated to smoking. Therefore, it is not surprising that our patients were less prepared to quit with 40% (22/55) in the preparation stage. After using the interactive education app, an additional 11% (6/55) of patients reported that they were ready to quit. This is consistent with earlier studies showing that even brief interventions can have a significant impact on smokers' attitudes [9,11,63]. This is particularly relevant given that extensive hospital-based interventions, though effective in increasing quit rates, have been difficult to translate into practice until recently [9,12]. Given the current health care climate, interventions that are not resource intensive and can reach a large number of smokers are needed, and these interventions should be designed to easily fit into the hospital workflow.

Participants' attitudes toward the mHealth education app in hospital were largely positive. Those who had more knowledge gains scored better on the attitudinal surveys suggesting that they perceived more value and benefits from the mobile app use. The majority of participants reported learning new information from using the mobile app, and more than 90% (51/55) of the participants reported that they would certainly recommend it to other smokers. It is conceivable that additional similarly designed modules incorporating smoking cessation counseling features, in addition to education might provide a feasible and effective approach to deliver smoking cessation counseling to large numbers of hospitalized smokers. Nevertheless, the impact on smoking cessation rates might still be modest in absence of outpatient follow-up [64-65]; whether these outpatient interventions might be facilitated by a mobile app used in a hospital remains to be determined. In a recent Cochrane review of inpatient smoking cessation programs, inpatient interventions that involved intensive counseling and continued for at least 1 month post discharge were associated with increased smoking cessation rates (OR=1.65; 95% CI (1.44,1.90)) [10,66]. If interventions based on mobile apps prove to be similarly successful, they could result in a major public health impact. More research is needed to develop and evaluate such interventions, to test their large-scale feasibility, and to extend their use beyond the hospital.

Strengths and Limitations of the Study

A strength of this study includes the demonstration of high acceptance of the mobile app by hospitalized smokers who are

in greatest need of smoking cessation intervention including minority patients with low socioeconomic status and limited education [67,68]. Despite these potential barriers, and the limited exposure to computers, the patients in this study found the mobile app usable and educational. Limitations of this study are the relatively small sample size, quasi-experimental design, and short follow-up. Specifically, although patients reported a higher readiness to quit smoking following the mobile app intervention, we did not determine whether these patients ultimately maintained a desire to quit following hospital discharge, and we do not know how many of them were successful in doing so.

Implications for Future Research

Statistically significant knowledge gain achieved by the mobile app users described in this study concurs with our previous studies [31-35]. As in the previous studies, knowledge gain coincided with improvements in attitudes and beliefs [50]. For example, computer-assisted depression education resulted not only in improvement in depression knowledge but also in decrease of mental health stigma [69]. In this study, besides increase in hazards of smoking knowledge, statistically significant improvements in self-efficacy and smoking attitudes were achieved. Also positive shifts in stages of change and decisional balance were identified, though they didn't reach statistical significance. This may be explained by a relatively small sample size and heterogeneity of study sample in terms of patients' background and smoking behavior. In addition, because hospitalized smokers included high proportion of individuals with high levels of nicotine dependence coupled with low socioeconomic status and limited education, more intensive and multicomponent interventions over prolonged period of time may be warranted to achieve sustainable change in smoking attitudes and behaviors leading to smoking cessation and lasting smoking abstinence. Thus, lack of significant change in Decisional Balance Scale in our study may be attributed to the fact that changing Pros and Cons balance in habitual smokers requires multifaceted intervention beyond a single encounter with a mobile app.

Multiple studies demonstrated that knowledge and beliefs about smoking are associated with key behaviors such as cessation and intent to quit. [70,71]. A consistent relationship between smoking status and belief in the harmfulness of smoking is well described [72]. Previous studies showed that those who evaluate smoking behavior negatively do so at least in part because they have knowledge of the negative health effects of smoking and this negative evaluation contributes to the intention to not smoke [73]. Our study concurred with these reports by showing various gaps in hazards of smoking knowledge in hospitalized smokers particularly on association of tobacco use and increased risk for leukemia, colon cancer, and cervical cancer. Knowledge gains attained after the mobile app use resulted in positive shifts of smoking attitudes and other behavioral constructs affecting quitting intentions. However, increasing knowledge about the harmful effects of smoking may not be sufficient for smoking behavior change and other factors such as social norms may play significant role [74]. Knowledge gain achieved by health education is generally considered a prerequisite for a successful behavior change and it may be helpful in affecting attitudes and beliefs however it is usually not sufficient to achieve lasting behavior change [53-56]. Different behavior change theories describe various constructs affecting health behaviors. For example, Theory of Planned Behavior (TPB) describes health behaviors and intentions including smoking using such constructs as attitudes, subjective norms, and perceived behavioral control [75]. Health education may be instrumental in affecting some of these constructs but additional intervention components are needed for successful behavior change. Based on underlying behavioral constructs emanating from corresponding behavior change theories such as TTM or TPB, effective mobile app for smoking cessation should be able not only educate but provide tailored counseling that corresponds to individual psychological, behavioral, and social characteristics of a smoker over a prolonged period of time. Interactive educational components aimed at increasing knowledge and tailored counseling components aimed at changing behaviors play complementary roles in mobile apps for smoking cessation. Thus, the mobile app described in this study may be a part of a multifaceted smoking cessation intervention delivered over a prolonged period of time in a tailored personalized way via multiple health communication channels as it was described previously [40].

Our study results concur with previous reports on positive use of hospital-based patient education [76,77]. Though earlier studies acknowledged significant potential of hospital settings as a fruitful venue for engaging patients in their care and empowering them with individualized health education and counseling, limited resources and personnel shortage were frequently identified as barriers toward widespread implementation of hospital-based patient education [76,77]. Previous studies reported that during hospital stays many patients experienced substantial inactive time coupled with recognition of seriousness of their health condition and desire to learn more about their care; however, staff availability for personalized health education was limited [78]. Our study demonstrated that mobile apps for personalized health education may help successfully address this barrier. Recently published studies confirm high potential of mobile apps delivered via tablet computers or smartphones for patient-centered hospital-based programs aimed at patient education, engagement, and empowerment [78-80]. Growing number of clinicians endorse use of tablets for personalized care delivery to their patients [81]. Employing more comprehensive computer-assisted interventions using a variety of behavioral constructs tailored to individual patient profiles over prolonged period of time may significantly enhance the performance of such systems in the future [79]. Larger scale studies with extended follow-up will be required to definitely evaluate the clinical benefit of this type of intervention [78].

Conclusions

A mobile app provides feasible and effective means to educate patients about the hazards of smoking in a hospital setting. The mobile app has significant potential in facilitating the reduction of racial disparities in health literacy as it pertains to hazards of smoking knowledge. Further research is needed to evaluate the cost-effectiveness and long-term effects of this promising patient engagement and empowerment approach.

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Conflicts of Interest

None declared.

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Abbreviations

CI: confidence interval
CO-ED: COmputer-assisted EDucation
DKS: difference in knowledge score
FTND: Fagerstrom test for nicotine dependence
KS: knowledge score
OR: odds ratio
SD: standard deviation
TPM: theory of planned behavior
TTM: transtheoretical model

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Original Paper

Mobile Phone Use Among Medical Residents: A Cross-Sectional Multicenter Survey in Saudi Arabia

Amr Jamal[1,2], MD, SBFM, ABFM, MRCGP, MBI; Mohamad-Hani Temsah[3]; Samina A Khan[4]; Ayman Al-Eyadhy[3]; Cristina Koppel[5], MBBS, BSc (biomedical); Michael F Chiang[6]

[1]College of Medicine, Department of Family and Community Medicine, King Saud University, Riyadh, Saudi Arabia

[2]School of Medicine, Medical Informatics and Clinical Epidemiology (DMICE), Oregon Health & Science University, Portland, OR, United States

[3]College of Medicine, Department of Paediatrics, King Saud University, Riyadh, Saudi Arabia

[4]Medical Informatics and E-Learning Unit, College of Medicine, Medical Education Department, King Saud University, Riyadh, Saudi Arabia

[5]Department of Medicine, School of Medicine, Imperial College, London, United Kingdom

[6]School of Medicine, Department of Ophthalmology & Medical Informatics and Clinical Epidemiology (DMICE), Oregon Health & Science University, Portland, OR, United States

Corresponding Author:
Amr Jamal, MD, SBFM, ABFM, MRCGP, MBI
College of Medicine
Department of Family and Community Medicine
King Saud University
PO Box 90714
Riyadh, 11623
Saudi Arabia
Phone: 966 114690822
Fax: 966 11469 0821
Email: amrjamal@ksu.edu.sa

Abstract

Background: Mobile phones have great potential for medical education, as they allow health care providers and students to access resources efficiently at the precise time at the point-of-care to help in informed decision making.

Objective: The objective of the study was to evaluate the prevalence of mobile phone usage among medical residents and to explore their attitudes, perceptions, and the challenges they experience when using mobile phones in academic and clinical practice.

Methods: A cross-sectional survey was conducted on all 133 residents in 17 different specialties across two large academic hospitals in Riyadh, Saudi Arabia. The Web-based validated questionnaire measured mobile phone platform preferences, and their uses in general and medical practice. The perception of confidentiality and safety impact of using mobile phones for communication and accessing patient's data was also explored, alongside challenges of use and how residents learn to use their mobile phone.

Results: With a response rate of 101/133 (75.9%) and mean age of 27.8 (SD 3.0) years, we found that 100/101 (99.0%) of participants were mobile phone users with mean duration of use of 5.12 (SD 2.4) years, and a range from 1 to 12 years. There was no significant difference in use between male and female respondents. A negative linear correlation was found between age and use duration (P=.004). The most common operating system used by participants was the iOS platform (55/101, 54.5%), with English the most commonly used language to operate residents' mobile phones (96/100, 96.0%) despite their native language being Arabic. For communication outside medical practice, chatting applications such as WhatsApp matched phone calls as most commonly used tools (each 88/101, 87.1%). These were also the primary tools for medical communication, but used at a lower rate (each 65/101, 64.4%). In medical practice, drug (83/101, 82.2%) and medical (80/101, 79.2%) references and medical calculation applications (61/101, 60.4%) were the most commonly used. Short battery life (48/92, 52%) was the most common technical difficulty, and distraction at least on a weekly basis (54/92, 58%) was the most likely side effect of using a mobile phone in medical practice. Practically, all participants agreed with the idea of integrating medical staff mobile phones with the hospital information system. Most residents described themselves as self-learners, while half learned from peers, and a quarter learned from the Internet. Only 7/101 (6.9%) had received formal training on the medical use of mobile phones. Over half of residents thought it was safe to discuss patients over their personal, nonencrypted email.

Conclusions: Mobile phone use among medical residents has become almost universal in academic and clinical settings. Thus, academic and health care institutions should support proper utilization of these devices in medical training and point-of-care decision making, while continuing to protect patient confidentiality.

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KEYWORDS

cell phones; mobile phone; telemedicine; medical education; medical residencies; educational techniques; patient care; communication methods; WhatsApp; Saudi Arabia; point of care technology

Introduction

Smartphones and Health Care

Over the last two decades [1], smartphones have been evolving rapidly in functionality and propagation. Smartphones combine a mobile phone with other features of personal digital assistance such as Internet browsing, email access, global positioning system navigation, touchscreen, motion sensor, wireless Internet for frequent interface/fourth generation (mobile telecommunications technology) connectivity, desktop synchronization, voice recognition, high-quality camera, large displays, as well as third party applications, commonly referred to as "apps" [2]. These functions turn the smartphone into a portable computer. They have great potential for medical education, as they allow health care providers and students to access resources efficiently at the right time at the point-of-care to support better decision making in patient care [3-7]. Faster processors, improved memory, and long-life batteries in concert with highly efficient operating systems capable of advanced functions have paved the way for apps that are beneficial for both personal and work environments.

Mobile phones in many ways are similar to personal digital assistant (PDAs), which have been studied well in health care education [4] and proven their value across a variety of apps. PDAs allowed health care providers to carry multiple references in their pocket, log clinical encounters, and tally of clinical time. Mobile phones are newer technologies with the expanded functions of cellular technology, Internet connectivity, and a wider range of specialized apps. Operating systems include, Google's Android, Apple's iOS, Research in Motion's BlackBerry, and Microsoft Windows Phone platform [5]. In addition to Internet browser access, a plethora of free and paid apps are on offer in each system's app distribution store. Here, individual users can browse and download apps as required, allowing for high personalization [8]. Mobile phones' cellular connectivity enables them to connect to Internet resources even when wireless networks are unavailable [5], making them particularly valuable in the clinical setting.

Health care workflow is highly mobile, encompassing multiple settings of care such as outpatient clinics, inpatient wards, emergency departments, operating theaters, intensive care units (ICUs), radiology departments, laboratories, etc [6]. Consequently, working in the health care system requires extensive mobility of health care providers as well as communication and collaboration among a variety of individuals, including colleagues, multidisciplinary teams, and patients. In addition, the nature of medical resident's work involves also continuous educational assignments and connectivity to educators and administrative teams.

Today, mobile phones serve a vital role in the practice of medicine, which ranges from patient monitoring and diagnostics to health education and communication.

Aim of the Study

The amount of research in the use of mobile phones in medicine is rapidly growing, but there are few high-quality studies answering questions about their use and impact on medical care and education [3]. Given the rate of uptake of mobile phones, their prevalence needs to be measured frequently as figures quickly become outdated. In addition, we seek to explore attitudes, perceptions, as well as challenges faced by their users. In particular, we are interested in their effect on confidentiality and security. We also wish to shed light on how residents view the role of the institution with respect to mobile phone use and how residents learn to use their devices and overcome barriers they encounter. A better understanding of the above is the first step in maximizing the technology's potential and limiting less desired consequences.

Methods

Study Design and Instrument

This is a cross-sectional survey based study using a self-administered structured questionnaire in the English language. The questionnaire included 22 validated questions distributed into the following sections: (1) general demographic information, (2) mobile phone preferences, (3) mobile phone general uses, (4) mobile phone medical-practice uses, (5) mobile phone learning/training uses, (6) communication tools/apps uses, and (7) mobile phones privacy and security issues.

Validity

The questions were generated based on a literature review about mobile phone uses among medical professionals and students [4,5,9-12]. Then, questions were drafted using the focus group technique utilizing the authors' personal and professional experiences. There were three experts in informatics that reviewed the questionnaire for content accuracy, validity, and reliability. A pilot study was conducted where the initial draft of the questionnaire was distributed to 30 professionals at King Khalid University Hospital (KKUH) ICU. The aim of the pilot study was to ensure the understanding and applicability of each question. Notes from pilot respondents were taken and questions were modified accordingly. A Cronbach alpha >.6 was recorded for the questionnaire during the pilot testing.

Subjects

Invitations to participate in the survey were sent to all of the 128 active residents enrolled in 17 different residency-training programs as per record of the two teaching hospitals as described below. No residents were excluded from the study.

Settings

The study was conducted at KKUH, Riyadh and King Abdul-Aziz University Hospital, Riyadh. Both are affiliated to King Saud University, Riyadh, Saudi Arabia. These university hospitals are the largest tertiary care referral teaching hospitals in Riyadh, with a major primary health care facility and various specialized departments, which make them priority targets for many medical students of the country for residency training.

Data Collection

We distributed the Internet questionnaire, via an email tool, available at a Web site, to the official email list of residents registered in the residency office in the two university hospitals during the period between January 2014 and April 2014. This Web-based survey tool was chosen because it was more reachable by all residents in different departments, in addition to residents who could be rotating outside the two hospitals, where it could be difficult to reach them through conventional paper surveys [13]. There were two reminders that were emailed to nonrespondents one-month apart. Moreover, printed posters encouraging participation with a direct Quick Response code link to the survey website were also provided. Posters were distributed among the hospital departments to motivate the residents to participate in the survey. In addition, we emailed all of the 17 chief residents of different residency-training programs of both university hospitals along with the advertisement poster attached. A text messaging communication service, known as "Tawasol", which is a Web-based communication service used to communicate with KSU staff members via short text messages, was used to send the official link of the survey to residents. Finally, residents were informally approached individually, asking whether they have participated in the survey or not, and to motivate them to complete it.

Data Analyses

The data were exported from SurveyMonkey into the Statistical Package for Social Sciences (SPSS), using standardized entry codes. For all tests, statistical significance was set at P <.05. Descriptive statistics were used to present means, SD, and percentage. In addition, student's t test, z-proportional test, and chi-square tests were employed to compare group variables between gender and demographic variables. Furthermore, the relationships of resident's attitudes toward using mobile phones in medical practice were assessed using regression analysis based on gender, specialties, and uses. The model was generated where all the selected variables were converted into binary data (disagree & agree). For multivariable analyses (regression), we constructed a dataset that had complete values for all relevant variables across observations, thereby, discarding the observations that had missing values for any of the variables involved in the regression analysis. The strategy was adopted to maintain comparability between models so that they could be developed from the same denominator. All analyses were conducted using SPSS version 21, 2013 (IBM SPSS, Inc, Chicago, IL).

Ethical Statement

All participants were informed about the purpose of the study and their electronic consent for participation was taken in the first Web page of the electronic survey. All participants' data are maintained in a secure fashion by separating participants' identifiers and associated data. All of the data were analyzed as a total population in a manner that individual privacy was maintained. Institutional Review Board (IRB) approval for this study was taken from the College of Medicine, King Saud University, Riyadh, Saudi Arabia (13/3914/IRB), and the Oregon Health and Science University Research Integrity Office (IRB00010913).

Results

Response Rate

Out of the 128 approached residents, 107 responded to the study (83.6%), six of them were excluded due to not answering all or most of the questions. However, surveys with missing answers that were not related to the main outcome variables were included in the analysis. Therefore, a total of 101/133 (75.9%) was analyzed.

Demographic Information

The mean age of participants was 27.8 years (SD 3.0), ranging from 23 to 38 years old. Most of the participants (59/101, 58.4%) were less than 28 years old. On further comparison, there was no statistically significant difference found between male and female age groups (chi-square test; P =.186). Males were higher in number and comprised a total of 63/101 (62.3%) of responded participants. The majority of respondents were in their first year (PGY-1) of residency training (55/101, 54.5%); see (Table 1).

Table 1. Demographic feature of the respondents.

Features		n=101	%
Age (years old)			
	Mean age (±SD)	27.8 (±3)	
	Below 28	59/101	58.4
	28-32	33/101	32.7
	Above 32	9/101	8.9
Gender			
	Male	63/101	62.4
	Female	38/101	37.6
Residency level			
	PGY-1	55/101	54.5
	PGY-2	13/101	12.9
	PGY-3	13/101	12.9
	PGY-4	7/101	6.9
	PGY-5	8/101	7.9
	Board eligible	5/101	4.9
Specialty (top seven only)			
	Pediatrics	14/101	13.9
	Internal medicine	12/101	11.9
	General surgery	11/101	10.9
	Otorhinolaryngology	11/101	10.9
	Ophthalmology	7/101	6.9
	Family medicine	6/101	5.9
	Obstetrics & gynecology	6/101	5.9

Mobile Phone Use

Almost all participants reported that they own and use mobile phones (100/101, 99.0%), with mean duration of usage of 5.12 (SD 2.4) years, ranging from 1 to 12 years. The relationship between duration of usage and age was found to follow a linear relationship (duration = 11.6 – 0.234 x age). Although this relationship was statistically significant (ANOVA; P =.004), it was not found to be a strong one (r =0.282).

The most prevalent language for operating residents' mobile phones was English (96/100, 96.0%), although Arabic was the native language of most participants (97/101, 96.0%). The operating systems mostly used were iOS from Apple (55/101, 54.5%), followed by Android (54/101, 53.5%), Blackberry (5/101, 5.0%), and Windows Mobile (3/101, 3.0%) in total (Table 2). Further analyses showed that (16/101, 15.8%) of participants were using two different mobile platforms, and only one participant was using three different mobile platforms concurrently. Out of iOS users, 10/45 (22%) were also Android users. All of the three Windows Mobile users reported using other devices at the same time.

Table 2. Mobile phone preferences.

		n=101	%
Mobile phone ownership			
	Yes	100/101	99.0
	No	1/101	0.9
Year using a mobile phone			
	Mean (±SD)	5.18 (±2)	
	Range	1-12 years	
Operating system used [a]			
	iOS	55/101	54.5
	Android	54/101	53.5
	BlackBerry	5/101	4.9
	Windows	3/101	2.9
Language used on mobile phone [b]			
	Arabic	4/101	4.0
	English	96/101	95.0

[a]Total is more than 100%, since more than one choice is allowed.[b]Total is less than 100%, since 1 participant missed answering this question.

Chatting Apps

Chatting apps (88/101, 87.1%) such as WhatsApp and LINE matched traditional phone calls (88/101, 87.1%) as the most often used nonmedical communication tools. Both of these tools, chatting apps (66/101, 65.3%) and phone calls (65/101, 64.4%), were also the highest ranked for practice-related communication, Figure 1 shows this. In general, drug references (83/101, 82.2%); medical references (80/101, 79.2%); and medical calculation (61/101, 60.4%) were the most commonly used noncommunication tools (Figure 2 shows this).

There were four out of five residents (73/92, 79%) that denied awareness of mobile phone medical apps provided by their institutes. There were no significant differences between males and females (chi-square; *P* =.347) or age groups (chi-square; *P* =.326). Most of the participants requested that their institutes should provide access to their patients' data via mobile version of electronic health records (82/101, 81.2%), mobile drug references (67/101, 66.3%), and medical references (59/101, 58.4%). Almost all of the participants (91/92, 98%) agreed with the idea of integrating medical staff mobile phones with the hospital information system. There were four out of five residents (73/92, 79%) that supported replacing their current hospital pagers with hospital-provided mobile phones.

Figure 1. Medical and nonmedical related usage of communication tools/applications (apps). King Saud University: KSU. The numbers on the y axis represent the percentage.

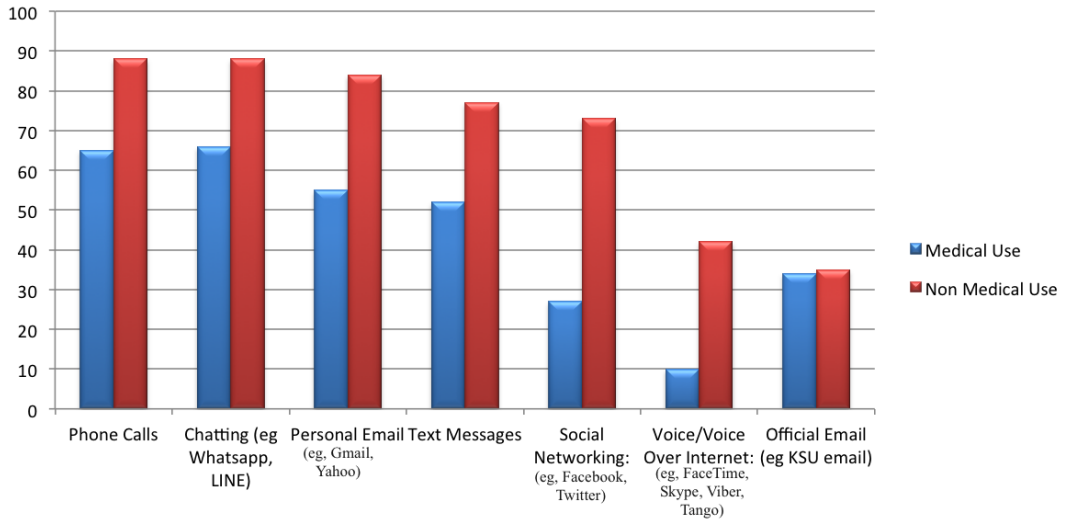
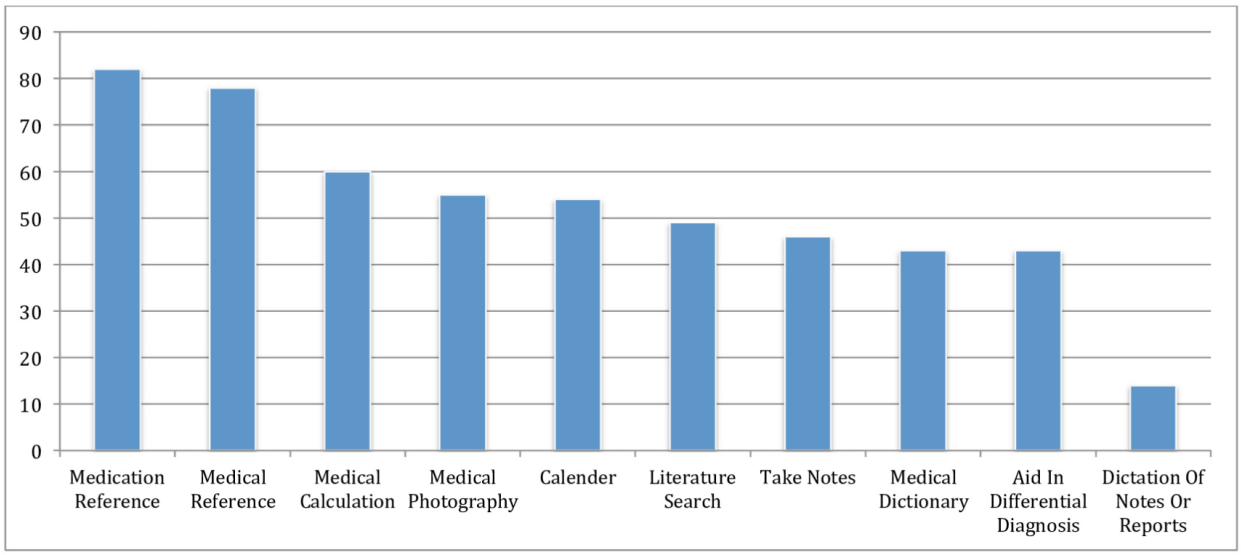


Figure 2. Medical-practice-related noncommunication applications (apps)/tools. The numbers on the y axis represent the percentage.



Learning to Use Mobile Phones in Medical Practice

When investigating methods of learning how to use mobile phones in medical practice, 84/101 (83.2%) of residents described themselves as self-learners, while 50/101 (49.5%) learned from their peers, while others (27/101, 26.7%) learned from Internet resources such as YouTube and blogs. Only 7/101 (6.9%) were exposed to formal training such as workshops or lectures and seminars about medical uses of mobile phones.

Reported Useful Uses of Mobile Phones in Medical Practice

Most participants (82/92, 89%) reported that smartphones were useful for staff communication, while 35/92 (38%) reported the communication with patient's family via mobile phone as harmful, though all the rest of the answers were neutral. In addition, the participants reported that mobile phones were useful in consultation (64/92, 69%), reviewing patient's lab/radiology results (79/92, 86%), and critical alerts about patients (71/92, 77%).

Technical Difficulties

To find out about the potential technical difficulties residents faced with their mobile phones, they were asked to rate the frequency of difficult situations they faced with their devices. Over half of the participants, (84/92, 91%), reported "short battery life" as a challenge faced on a daily basis (Figure 3 shows this) with 28/92 (30%) reporting that mobile phones were distracting them from their work on a daily basis, and 26/92 (28%) were distracted by smartphones on a weekly basis (Figure 4 shows this).

Figure 3. How frequently did you experience these technical problems on your mobile phone? The numbers on the y axis represent the percentage.

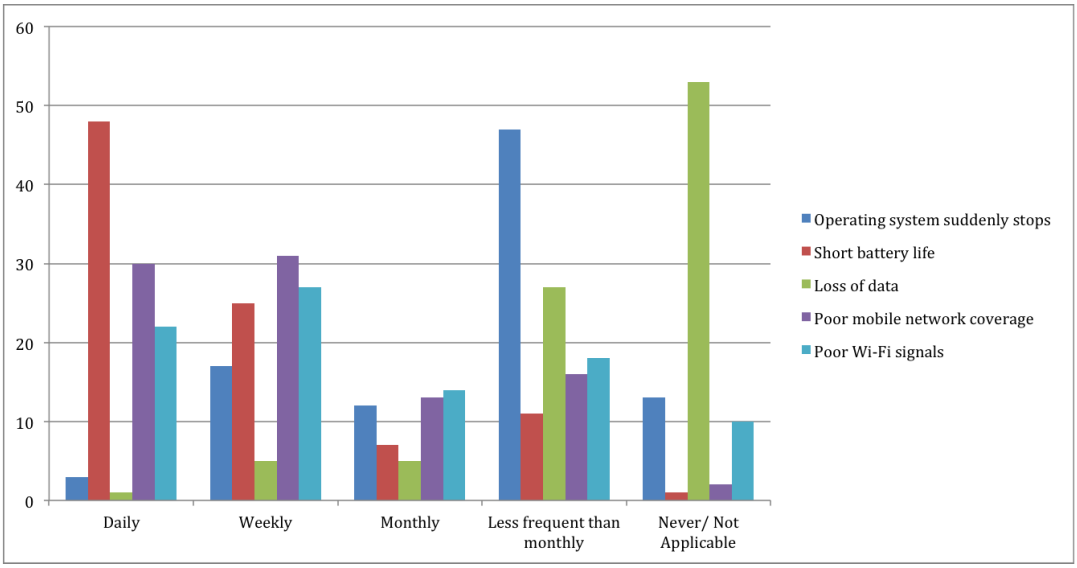
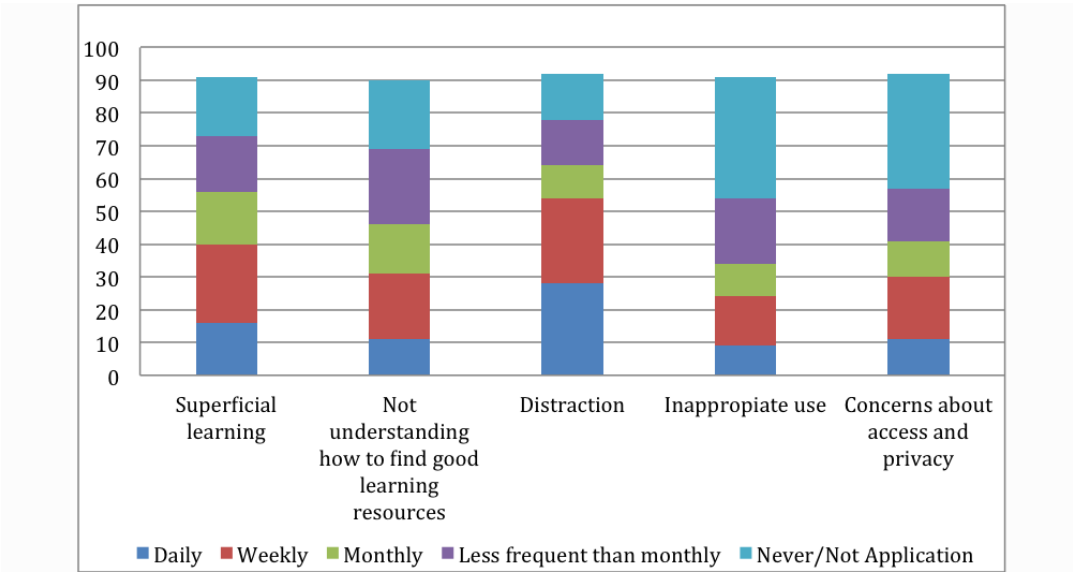


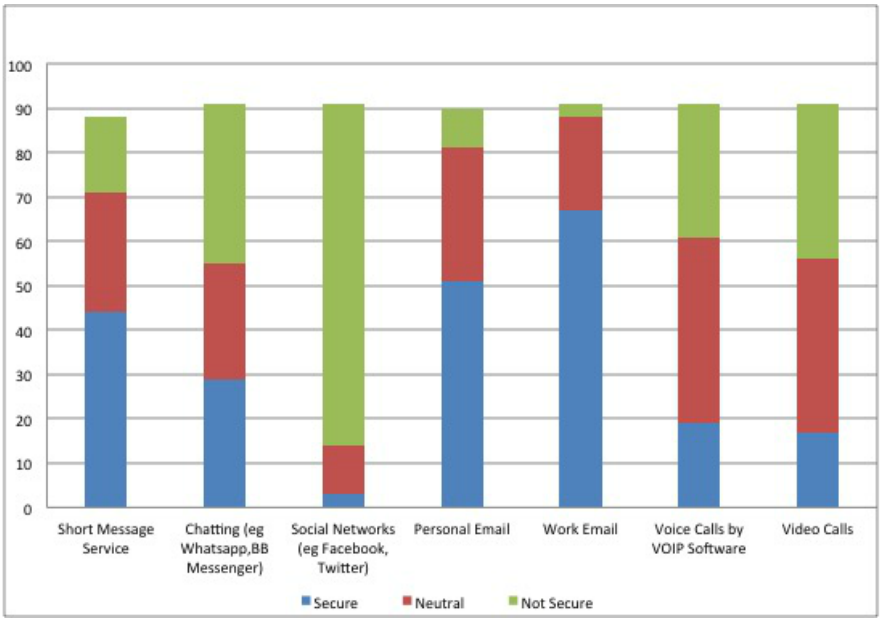
Figure 4. How frequently did you experience these challenges on your mobile phone? The numbers on the y axis represent the percentage.



Safety of Using Mobile Phones in Medical Practice

Most of the participants thought that using official email (67/91, 73%) and personal email such as Gmail, Hotmail, and Yahoo (51/92, 55%) were safe and secure in discussing patients' details. On the other hand, most participants reported social networks, such as Facebook and Twitter (77/92, 84%) were not safe to discuss patients' data (Figure 5 shows this). Female residents were more conservative in perceiving the safety of mobile chatting apps (χ^2_2=8.7, P =.012, phi= 0.311) and voice calls apps such as Skype (χ^2_2=9.7, P =.008, phi= 0.327).

Figure 5. Are these communication application (apps)/tools secure in discussing your patient's details. The numbers on the y axis represent the percentage.



Discussion

Principal Findings

Due to the increased global adoption rate of mobile technology in medical practice [8], it is not surprising that the adoption rate found (100/101, 99.0%) in our survey is much higher than previous studies locally and abroad. A comparable study conducted in Riyadh a year prior to this study, but in a much smaller sample size showed an adoption rate of 45.5% among medical residents, with a duration of usage between 5 to 9 years [14]. In the United States, the adoption rate plateaued since 2011 at a low- to mid-80 number in terms of physicians using it for professional purposes [15-17]. In the United Kingdom, a 2012 study quoted a prevalence of 75% [8].

Besides the significance of "how many" residents are using mobile phones, similarly important is "what quality" of apps are being used by these residents. Mobile phone apps for clinical use are a vital aspect for the training residents, who may continue to use such apps for their actual patients' care. Many studies focused on this issue. For example, Vohralik et al [18] assessed the reliability and validity of a mobile phone app to measure joint range. They concluded that the apps they assessed were both reliable and valid, provided a low-cost method for measuring range of motion, and were easily incorporated into

clinical practice. In another study by Man et al [19], they found that a mobile phone app was effective for both increasing confidence in depression treatment and educating physicians. However, they recommended that future studies were still needed to evaluate the effectiveness and impact of mobile phone apps on medical education and postgraduate training [19]. Sampognaro et al [20] reported that mobile devices offered the potential to enhance prerounding efficiency for medical students and residents. They suggested a customizable Evernote-based system for reproduction by interested students [20]. Recently, Jin and Kim [21] described their three-phases evaluation of a "Tool for Healthcare Smartphone Applications". They concluded that the evaluation tool they developed and tested in their study was an appropriate and widely applicable tool to evaluate health care mobile phone apps to determine if they are reliable and useful [21].

Our study showed a significant negative correlation between age of participants and duration of mobile phone use in their lives. This could be explained by the expectation that younger residents are using mobile phones earlier in their education.

Although Android is the most common mobile platform in the general population [22], Apple's iPhone iOS was more predominant in medical population, as was found in this study (55/101, 54.5%), which is close to other international surveys (56%) [23].

Most Commonly Used Apps

Emails are still the primary method of correspondence in health care [24], but are not that common in communication with patients [25,26]. Similarly, communication apps, such as WhatsApp and LINE, usage is gradually wide spreading as much as phone calls as found in this survey, and other literature [27-30]. Our survey showed an increasing prevalence of using mobile nonofficial emails and chatting apps for medical-practice related usage. This is alarming given that 51/90 (56%) of our respondents perceived that it was safe to use their personal nonofficial emails to discuss their patients' data.

As shown in this study and other previous studies, drug information apps were the most commonly used apps used in clinical settings with a range of 72-100% of residents and physicians [10,14,16,31]. Although our survey did not ask about the use of mobile phones to take clinical photos, other recent studies have reported that the increasing number of physicians, especially dermatologists, capture and store patients' photos in their mobile phones [30,31].

Learning Methods

In contrast to most of the other technologies applied in medical practice, the vast majority of mobile phone users, as stated in this study and other studies [32], required only a short time to self-learn how to use their mobile phones for accessing point-of-care medical information at the bedside and engaging in self-directed learning. This highlights their ease of use and potential as a good platform for delivering technology-assisted software. At the same time, we would do well to provide more formal support and training. This would also help residents be more aware of official apps provided or approved by institutions.

Implications for Practice

A very high percentage of participants (88.9% of male and 90.0% of female participants) strongly agreed that PDAs had improved their performance [14].

The use of handheld computers has improved patient documentation through more complete recording, fewer documentation errors, and increased efficiency. Handheld computers provided easy access to clinical decision support systems and patient management systems, which improved decision making for patient care. Handheld computers saved time and gave earlier access to recent information. There were also reports that handheld computers enhanced work patterns and efficiency [33]. In another study, Tran et al [26] reported on the personal mobile phones uses among clinicians. They found that personal devices were used to communicate with their medical teams and health care professionals. Participants in that study from four academic teaching hospitals in Toronto, Ontario, reported their understanding of the potential risks associated with communicating confidential health information via their personal mobile phones, but appeared to favor efficiency over privacy issues. From survey responses, 9/23 (39%) of the residents reported using their personal cell phones to email or text patient related information that may have contained patient identifiers. Although some residents in that study were observed using personal mobile phones for nonwork-related activities, personal uses were assessed as infrequent [26]. Likewise, in addition, Wu et al [34] described a hospital setting with a newly implemented communication system with support for physician handover and secure messaging. They found that a majority of their medical trainees (82.8%) and nursing staff (78.3%) agreed that such a system helped to speed up their daily work tasks. Most of them also agreed that the system made them more accountable in their clinical roles [34].

Frequent challenges of mobile phone adoption in medical practice found in our survey were limited-battery-life and low-network-coverage. Other studies have raised the awareness of other obstacles such as small screen size, potentially mistaken data input, viruses, magnetic interference with medical devices, hampering of patient-physician interactions, loss or theft, and breaches of data privacy and security [8].

Mobile phone-caused distraction is defined as any interruption of a hospital clinician's primary task caused by the internally or externally initiated use of mobile phone [35].

Conclusions

Mobile phone use among medical residents in various medical specialties has become almost universal in health care settings. Despite some limitations, mobile phones play a weighty role in residents' day-to-day medical practice and residents use them beyond communication. This should alert academic institutes about proper utilization of these devices in medical training and point-of-care decision making, while at the same time ensuring patient's confidentiality. This may include, but not limited to: suitable training on the proper utilization of these devices, integration of hospital information systems, enabling trainees to access patient's data on their mobile phones, accompanied

by adoption of comprehensive data confidentiality agreement, policies, and procedures. Looking to the future, medical institutions need to incorporate proper use of mobile phone technology and help maximize its potential in their training strategies.

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Conflicts of Interest

None declared.

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Abbreviations

apps: applications
ICUs: intensive care units
IRB: Institutional Review Board
KKUH: King Khalid University Hospital
PDAs: personal digital assistant
PGY-1: first year
SPSS: Statistical Package for Social Sciences

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Original Paper

Use of iPhones by Nurses in an Acute Care Setting to Improve Communication and Decision-Making Processes: Qualitative Analysis of Nurses' Perspectives on iPhone Use

Maureen Farrell[1], AA

University of Melbourne, Victoria, Australia

Corresponding Author:
Maureen Farrell, AA
University of Melbourne
Parkville
Victoria, 3010
Australia
Phone: 61 3 9035 ext 5511
Fax: 61 3 9035
Email: maureen.farrell@unimelb.edu.au

Abstract

Background: Smartphones and other mobile devices are having and will continue to have an impact on health care delivery in acute settings in Australia and overseas. Nurses, unlike physicians, have been slow to adopt these technologies and the reasons for this may relate to the status of both these professions within the hospital setting.

Objective: To explore nurses' perspectives on iPhone use within an acute care unit. We examined their experiences and views on how this device may improve communication and decision-making processes at the point of care.

Methods: Two focus group discussions, using a semistructured interview, were conducted over the trial period. The discussions focused on the nurses' experiences regarding ease of use, features, and capabilities of the device. The focus groups were recorded, transcribed, and analyzed using semistructured interview questions as a guide.

Results: The positive findings indicated that the iPhones were accessible and portable at point of care with patients, enhanced communication in the workplace, particularly among the nurses, and that this technology would evolve and be embraced by all nurses in the future. The negatives were the small screen size when undertaking bedside education for the patient and the invasive nature of the device. Another issue was the perception of being viewed as unprofessional when using the device in real time with the patients and their family.

Conclusions: The use of iPhones by nurses in acute care settings has the potential to enhance patient care, especially through more effective communication among nurses, and other health care professionals. To ensure that the benefits of this technology is woven into the everyday practice of the nurse, it is important that leaders in these organizations develop the agenda or policy to ensure that this occurs.

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KEYWORDS

acute care; clinical decision making; communication; iPhones; nursing

Introduction

Smartphones and other mobile devices are having and will continue to have an impact on health care delivery in acute settings in Australia and overseas. Nurses, unlike physicians, have been slow to adopt these technologies and the reasons for this may relate to the status of both these professions within the hospital setting. Physicians are often given easier access to the technology needed to run health care apps and administration seems to have a more relaxed attitude toward the use of these devices by these professionals [1,2]. Initially, personal digital assistants (PDAs) [3-16] were first used; however, these have now been surpassed by the smartphone—a PDA with multiple capabilities. These phones offer voice and text communication, advanced computing, and communication capability, including Internet access and geo-positioning systems. Other features include on-board personal management tools, high-quality cameras, and recording devices. Current research suggests that

smartphones may support aspects of clinical diagnoses and treatment [17,18], yet there has been limited studies on whether the devices improve decision making and communication at the point of care. The literature that was available highlighted the various means of communication and how these can be used to reduce communication errors [19,20]. Another study suggested that mobile communications may have a negative impact on informal interaction between health care professionals and this may require sociotechnical change [21,22].

Recent systematic reviews highlighted the increased use of smartphones and how they are becoming a necessity for clinical use among health care students and professionals [1,17,23-25]. Real-time evidence-based clinical information was also considered important at the point of care, as it is common for clinicians not to seek answers to clinical queries after completion of a patient encounter [26]. Bedside access to patient information, or access from anywhere, through smartphone use, was accentuated, with a focus on security of personal data [27-29]. Drug reference apps, e-textbooks and references for disease diagnosis and treatment, and medical calculators were reported as most useful for clinicians and students.

The vast amount of medical information, the rapid growth in new pharmacotherapies and technologies, increasing time constraints on clinicians, escalating pressure to reduce costs, and substandard systems for delivery of care make it nearly impossible for clinicians to provide high-quality, error-free care on a consistent basis. In Australian hospitals, the most reported adverse events (ie, incidents in which harm resulted to a patient receiving health care) are infection, falls resulting in injuries, and problems with medication and medical devices [30]. In most cases, a significant number of the errors are the result of faulty system designs and conditions, and not due to individual negligence or incompetence. It is well documented in the literature that mobile technologies have the potential to reduce medical errors or adverse events [20,31,32]; however, there is also the potential for unintended consequences, such as technology-induced errors and distraction [10,33,34]. With the increasing complexity of the health care system, it seems that smartphones, like the stethoscope, are becoming a necessary work tool for clinicians—the challenge is to maximize the benefits of this technology while reducing the negatives.

The registered nurses (RNs) in this study used the smartphone in an acute care unit that treated patients with diseases such as breast and ovarian cancers, obesity, and diabetes, all of which required ongoing support. In Australia, there is limited literature on the use of smartphones in clinical practice, yet it has been embraced in some areas. The expected outcomes of this study are improved communication and decision-making processes within the acute care unit by nurses and other health care professionals. This may indirectly lead to more efficient health care delivery, with reduction in costs related to medical errors, especially in the area of medication prescribing and administration. Increased efficiency in execution of patient care may result as the nurses will have more time to provide direct patient care. The smartphones can also be used for education of patients, especially those with diseases that require ongoing support. There may also be a cultural change within the unit, that is, nurses and other health professionals embrace the use of these mobile technologies, so that they are embedded in the workplace and in the workflow.

Methods

Study Objective

This study used both quantitative and qualitative methods to investigate the use of smartphones by nurses in an acute care setting. This paper focuses on the qualitative data that were captured in focus group discussions to explore the nurses' perspectives on the use of smartphones for communication and decision-making processes.

Sample and Setting

The research was undertaken in the Gynecological Ward at Royal Women's Hospital (Melbourne, Australia). A total of 20 RNs were purposively selected to participate in the project. All received an 8-GB iPhone 5 (mobile device selected for this study), a waterproof case, and an iTunes card to the value of AUD $30 (donated by Apple Australia) to download relevant software apps—MIMS Drug Information, MIMS Drug Interact, MedCalc, and PubSearch. The key features of the device included a 4-in. Retina display, an Apple-designed A6 chip for faster performance, and a longer battery life. JB Hi FI and Telstra, the vendors for this project, provided the equipment and a AUD $60 monthly plan for each nurse. They also conducted a 2-hour training session for the participants in iPhone use at the commencement of the study and provided ongoing support for any technical issues, if needed, throughout the 12-month trial period. To ensure that the AUD $60 plan was not exceeded by the nurses, Telstra provided tracking of the iPhone by text messages and voice usage. The Human Research Ethics Committee of the Royal Women's Hospital approved the study.

Data Collection and Analysis

A semistructured interview was used in the focus group discussions. The participants were asked to describe their general impressions of the iPhones; any impediments or barriers encountered when using the iPhones; support they received from the training team; impact of the iPhones on their communication processes with other nurses and health care professionals, on their decision making, and on the culture within their work environment. The audiotapes were transcribed verbatim and the content was analyzed using the semistructured interview as a guide for identified themes.

Results

The narrative data were analyzed around the questions used in the semistructured interview with scope for follow-up questions.

General Impression, Impediments, and Barriers Encountered When Using the Mobile Device

Most of the nurses found the iPhones easy to use as reflected in the following statement:

> *A lot of people who'd already used one [an iPhone] picked it up quite quickly.*

The physical size of the screen was problematic and was deemed too small to use at the bedside and to research information. The speed processing and graphics were reported as fine yet battery life was reported as problematic for some nurses. The main reason for the latter was problems with the charger for some of the devices. They were faulty and had to be replaced by the vendors. Others were simply not recharging the device at home, and thus, to overcome this limitation, some nurses brought a charger to work. With regard to the data usage, there were inconsistencies in how often this was checked. Some respondents checked their usage regularly, whereas others did not know how to do so. Consequentially, a participant reported going over the data allowance and identified the problem to be related to connection error with the iPhone,

> *I went over on my data allowance...because it wasn't picking up the Wi-Fi network here.*

The main impediments reported for using the iPhones were reported as the physical size of the screen, connectivity issues, commonality for American apps to be more available/accessible, and the potential generation gap in technology. Various nurses announced these specific accounts for these evidential barriers. For example, as one nurse noted,

> *The actual size of the phone and screen...too small. I think a printout is easier.*

There were repeated responses regarding the preference to hardcopies for patient education, *I don't think there's a demand for it in your patient care...and that you need to be using the Internet to educate the patient. We've got booklets from the Cancer Council and things like that...I'd much prefer to give to a patient*

> *If they've got a physical booklet in front of them, it's going to be a lot better than a website.*

With regard to connectivity issues, one nurse said,

> *I couldn't load up the bundle...the website I need...I think there's a security control here.*

Another challenge certain nurses experienced was the difficulties in finding Australian-normed apps instead of American (with reference to drug calculations),

> *A lot of it is American...there's acronyms for things that I haven't heard of...I'm struggling to find an Australian standardised app.*

The theme of the generational gap emerged from this nurse,

> *I think specifically the older nurses, who haven't used or who haven't had an iPhone were thrown in the deep end...and went this is too hard.*

The final and potentially most pronounced theme was the nurses being perceived as unprofessional, which inhibited and discouraged the iPhone use, especially at the bedside, as reflected in these statements:

> *Doing your own personal stuff on work time when you should be looking after their relative or their family member.*
>
> *I've found I have to explain that it's a work phone...because I feel it looks unprofessional.*
>
> *I feel like it's rude to them [patients] to be on the phone.*

Similarly, a nurse noted that the physical factor of having a phone with you could consequentially have negative implications as "it can intrude on those conversations."

General Impressions About the Support From the Training Team

The majority of the respondents stated that they did not receive enough training and support at the initial stages of the study. Downloading the software apps was problematic for some of the nurses and believed that this should have been done before they had received the device. In addition, some nurses reported technical complications relating to login details

> *It took a whole month for me to figure out all the logins.*

Some also noted a *lot of teething issues* at the commencement of the project. In terms of ongoing support, certain nurses disclosed that it was a matter of practice and "*getting used to the iPhone,*" whereas another nurse noted they require "continuous education." The nurses supported each other as noted in the following response:

> *I contacted IT and they helped me and so I was able to sort of set everyone else up.*

Similarly, there appeared to be a collaborated effort with regard to the types of apps downloaded,

> *Someone downloads and says that's a good app, so all the others download it as well.*

The good apps cited by the nurses were BreCan (patient education, nursing needs, and updated clinical information), Coloplast (wound care and dressing selection), LactMed (medications that can be used when breast feeding), MIMS (pharmacological database for checking drugs), and MedScape (point-of-care decision making including drug administration). With regard to iTunes accounts there were inconsistent reports of set ups as exemplified by the following statements:

> *Everyone set up the iTunes account, so there are a few things downloaded.*
>
> *Half of them didn't have an iTunes account.*

Only 1 respondent stated seeking assistance from Apple, where they went into an Apple store and downloaded apps with assistance in the store.

Impact of iPhones on Communication Processes With Other Nurses and Health Care Professionals

Communication was the dominant reason for iPhone use. One respondent noted,

> *I would think 95% of the time it's for communication between staff.*

The most prevalent type of communication was phone calls and texting, depicted with the following responses,

> *I would say the majority of the time I use them for calling.*

I would text more often...but not always...because it looks like you're texting socially." One participant reported the issue of response time with text messages,

> *They don't get answered as fast...don't know if they got it.*

Participants also reported using the iPhones to check their emails: *getting emails has also been useful.* There were varied responses with regard to how often the nurses used the iPhones; however, the average was around 2-4 times/shift. The general consensus among the respondents was that communication between nurses had improved,

> *It's very good communication between us.*
>
> *I think it has been really good communicating between staff.*

The nurses reported that the main reasons for making contact with other nurses was centered on changing shifts, social agendas, and checks related to patients. There were no reports of using the iPhones for organizing professional development sessions, although some of the nurses reported that they had organized meetings for staff via the iPhone email or arranged meeting points using the device.

Communication with other health care professionals yielded varied responses:

> *I haven't used it to page any doctors or anything though.*
>
> *Sometimes I think it's easier to page them by their phone.*

By contrast, effective use of the device was also reported, as one nurse noted,

> *I've called people directly...leave my number and the doctor's call me back.*

The most common reasons for contacting doctors included medication and intravenous (IV) fluid orders and reviews. In terms of these health care professionals' responses, most nurses appeared to incur positive feedback, as the following inferences indicate,

> *Some doctors are on board...[doctor] called me on my iPhone.*
>
> *Their awareness of it is good as well, for them to be able to contact us.*
>
> *Ward clerks and the nurse in charge use it to contact you if your patient needs to go to imaging or needs to be transported.*

Yet other nurses had experienced less positive encounters and felt that there was a lack of knowledge about the project, as one key informant implied,

> *A lot of clerks still yell for me.*

Similarly, the nurses reported inconsistent experiences with speed of reply from doctors,

> *I needed a fluid and blood order for a patient and I paged one of the doctors. It had been a good half an hour so I paged again and nothing. So I found another doctor and then they got back to me straightaway.*

There was a continuous theme that emerged throughout the interviews that indicated the project was a transitional process, to which the nurses and other staff adapted,

> *At the start of the trial the doctors were quite unsure of it...because they weren't told about it...seem fine with it now.*

There was frequent reporting that other health care professionals (most commonly referring to doctors) use similar technologies:

> *They use their phones all the time.*
>
> *Look up their phones a lot more than us.*
>
> *The doctors download this app and you communicate between the apps, and that's the paging system.*

This example highlighted the notion that doctors are already utilizing technological advancements efficiently.

In the case of a clinical emergency, the first reaction from the respondents was generally not to use the iPhone,

> *I don't think it [iPhone] would be realistic to ever use in an emergency, because with bedside phones it's a four digit number...so it's just easier to use the bedside phones.*

However, with further deliberation, the nurses disclosed the benefits of the iPhone if they did not have access to a phone, as reflected in the following statements:

> *We had a patient with something going on with their heart...Paged [doctor] and they called back within 30 seconds...on the ward within two minutes. That was really good...and we didn't have to leave the patient.*
>
> *If you were somewhere else in the hospital, not near a phone...probably handy... in a situation where, just say you were down the car park and its dangerous or in the lift, and you're by yourself and something happens.*

Impact of iPhones on Decision Making and Culture Within the Work Environment

Very few nurses reported using decision-making software apps when providing care. The common reason was generally based on the habit of going to a computer, as indicated in the following comments of key informants,

> *I still find myself going to the computer to look at that [MIMS], it's just probably more habit.*
>
> *I just find it quicker to jump on the computer and I did MIMS today. I totally forgot about the iPhone.*

The nurses reported that they had experienced a variety of responses from patients regarding the nurses using their iPhones for direct care. There was a continuous theme of the nurses experiencing a degree of unease when using the iPhones at the bedside, and noted the inappropriateness of answering calls during particular times as the following nurse articulated,

> *I always think when I ring another staff member and they're in with the patient...having discussions about dying and death...then the phone goes off...if I was*

> *talking and giving some education [to a patient] it would be so rude...to answer my phone.*

The majority of nurses stated that the small screen size of the phone made it inappropriate to use at the bedside, especially with older patients:

> *If someone is elderly...showing a tiny little screen about the website or something...I think a lot of our education and information for patients is a print off that they can take home and read. It's not something you sit there and go through or flick through on the phone with them.*

Yet some did admit that they *"looked a few things up"* when they needed information quickly or they did not have access to a computer.

Furthermore, with regard to cultural change, several nurses reported that the iPhones were the beginning *"of what's to come"* and were integral to modernizing the workplace. For example, one nurse remarked,

> *The culture today is that everyone is on the phone...it does save a lot of time. It has the potential to be brilliant. I think the biggest concern for all of us was that we didn't get a really good set up at the start.*

There was also the belief that there was a degree of evolution and gradual change in culture as exemplified by the following comments from nurses:

> *Things just take time to sink in, I think this will be more useful gradually. Once we use it more and get used to use it. I think it's the future, or it's the current future. Have to get into this.*
>
> *Junior nurse might use the Internet a lot on their iPhone as compared to the senior nurse who has a lot more knowledge. So it might be really helpful for a junior nurse.*

Another respondent stated that

> *She had been nursing for nearly nine or 10 years [and] never had this opportunity really to have a phone and to look up apps and to show patients that*

One nurse with reference to technological advancements believed that a device with a larger screen, such as an iPad, would be next to every bed in the future. Others shared this sentiment,

> *Now they're talking about iPads...bigger screen...that'd be good for education.... I'd feel more comfortable showing them something on an iPad more than getting out my tiny little phone.*

However, some reported that

> *iPads are not good for communication because you can't call on it or put it in your pocket.*

Discussion

Preliminary Findings

Communication and decision-making issues among health care professionals are a major problem in the clinical area and often result in medical errors, that in most cases, are preventable [19,20]. The use of iPhone by nurses to address this problem identified varying themes that are related to practical use, impediment and difficulties encountered, impact the devices had on their communication and decision-making processes, and future use. As most of the nurses were from the Generation Y age group, they found the iPhones easy to use and had no problem with speed processing and graphics, yet staying within their daily data allowance. Problems encountered were the small size of the screen and the battery life, findings that were consistent with similar previous studies [35,36]. It is interesting to note that screen size was a problem; however, this was related to downloading PDFs or information that was difficult to read, not to apps that had been specifically designed for iPhone. Another impediment articulated by most of the nurses was being perceived as unprofessional when using the device with the patient or family at the bedside. They felt it was rude to answer the iPhone or attend to a text when administering direct care or speaking to family members. This has been identified in other studies where nursing and allied health professionals found it disruptive when doctors answered calls during interprofessional rounds [21,37]. However, explaining the reason for using a mobile device to the patient was found to have a positive effect on patient-physician interactions and communications [38]. In this study, the nurses did inform the patients and their family that it was a work iPhone and there was a flyer in each room stating that the nurses would be using the iPhone to assist them with the decision-making and communication processes. With regard to support from the training team, most nurses reported that this was inadequate at the beginning of the trial period, and so they sought assistance from each other to find solutions to the problems encountered (eg, downloading software apps). Ongoing support was not required as most nurses improved with practice and became familiar with the use of the iPhone.

Communication was identified as the major reason for iPhone use with the most common medium being phone calls and texting, undertaken at least two to four times/shift. The general consensus was that communication between nurses had improved with the focus being on checks related to patients, changing shifts, and social agendas. Contacting doctors and other professionals within the work environment varied, as some used the iPhone whereas others still used the paging system. The most common reasons for contacting doctors were for IV fluid orders and medication reviews. Clinical emergencies at point of care were not a high priority for iPhone use as there was a bedside phone; yet, most nurses acknowledge that they would use the device if they did not have access to this phone, and this was the case for some patients with cardiac problems. Others stated that they would use the iPhone for their own personal safety, for example, in car parks or trapped in lifts. The ward clerks and the nurse in charge also contacted the nurses on the iPhone mainly for transportation of patients to imaging or other areas within the hospital, and most believed this was very beneficial. What did emerge from these narratives, which is significant, was the prolific use of smartphones by physicians. All the nurses recognized how far advanced they were in the use of these technologies, not only for efficiencies in clinical practice, but also for communication among

themselves. This finding is consistent with the literature reports [1,2].

Using the iPhones for decision making and educating patients/family at the point of care was not fully embraced by all nurses. Most felt a degree of unease, as stated previously, and were inclined to look up information on the ward computers rather than the iPhone. When educating patients/family, the main issue was screen size, especially for older people, and the print material was more accessible. Yet at the end of the trial period most agreed that they did use the iPhone to look up information quickly, particularly when the ward computers were being used by other health care professionals. The information most sought was related to drug administration, which is evidenced by the literature [2]. When asked about future use of iPhones, most agreed that it will only be a matter of time before these technologies are integrated into their practice, as a necessary clinical tool. Some believed the iPad would be more beneficial as it had a larger screen; however, others reported that it was not as accessible and mobile as the smartphone.

These findings suggest that iPhone will be adopted by nurses in clinical practice, primarily for communication between themselves and doctors. Although the device was not used as much for decision making, this will evolve and the ideal software apps developed will need to assist with workflow, offer quick information about medications, illnesses, or symptoms, and coordinate multiple activities.

Conclusion

To our knowledge, this study is significant, as it is the first in Australia to comprehensively investigate the use of iPhones by nurses in acute care unit to enhance communication and decision-making processes. As stated previously, this study focused on the qualitative aspect where the nurses' perspectives on iPhone use within this environment were explored. The most significant themes that emerged from the narratives were that all the nurses embraced the use of iPhones and believed that the device will become a necessary clinical tool, like the stethoscope. This is a promising finding as nurses, unlike physicians, have been slow to adopt mobile technologies in Australia and overseas. The challenges now lie with nursing leaders and managers, in both the education and clinical sectors, to ensure that these technologies are adopted. Overall, it is clear that more research and development are needed to fully realize the potential benefits of these technologies, especially the impact on patient health outcomes.

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Conflicts of Interest

None declared.

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Abbreviations

IV: intravenous
PDAs: personal digital assistants
RNs: registered nurses

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Original Paper

Mobile Electronic Medical Records Promote Workflow: Physicians' Perspective From a Survey

Julian Duhm[1*], Dr, MSc; Robert Fleischmann[1*], MD; Sein Schmidt[1,2], MD; Hagen Hupperts[3]; Stephan A Brandt[1], MD, PhD

[1]Vision and Motor System Research Group, Department of Neurology, Charité - Universitätsmedizin Berlin, Berlin, Germany

[2]Clinical Research Unit, Berlin Institute of Health, Berlin, Germany

[3]Department of Information Technology, Charité - Universitätsmedizin Berlin, Berlin, Germany

[*]these authors contributed equally

Corresponding Author:
Robert Fleischmann, MD
Vision and Motor System Research Group
Department of Neurology
Charité - Universitätsmedizin Berlin
Charitéplatz 1
Berlin, 10117
Germany
Phone: 49 30 450 560045
Fax: 49 30 450 560911
Email: robert.fleischmann@charite.de

Abstract

Background: As a result of demographic changes, physicians are required to deliver needed services with limited resources. Research suggests that tablet PCs with access to patient data may streamline clinical workflow. A recent study found tablets with mobile electronic medical records (EMRs) can facilitate data retrieval and produce time savings across the clinical routine within hospital settings. However, the reasons for these time savings, including details on how tablets were being used, remain unclear. The same applies to physicians' perceptions of this tool within an inpatient setting.

Objective: This study examined physicians' perception of tablets with EMRs in an inpatient setting. The rationale was to identify both subjective and objective factors that impacted the successful implementation and use of tablets running an EMR.

Methods: We developed a 57-item survey questionnaire designed to examine users' perception of and attitude toward tablets, which was administered to 14 participating physicians following 7 weeks of tablet use. Five participants volunteered to participate in a second study that investigated physicians' patterns of tablet use within the EMR environment by digitally tracking and storing usage behavior. Statistical analyses of questionnaire results included mean values with their bootstrapped 95% confidence intervals and multivariate analysis of variance to identify predictors of tablet use.

Results: Physicians reported high degrees of satisfaction with the tablets. There was a general consensus among physicians that tablet use streamlined clinical workflow through optimized data retrieval (rated 0.69, 0.23-1.15 points better than control) and improved communication with patients and other physicians (rated 0.85, 0.54-1.15 and 0.77, 0.38-1.15 points better than control, respectively). Age ($F_{3,11}=3.54$, $P=.04$), occupational group ($F_{1,11}=7.17$, $P=.04$), and attitude toward novel technologies ($F_{1,11}=10.54$, $P=.02$) predicted physicians' satisfaction with the devices and their motivation regarding their further use. Tracking data yielded that only a few of the available functions were used frequently.

Conclusions: Although tablet PCs were consistently perceived as beneficial, several factors contributed to the fact that their full potential was not fully exploited. Training in functionality and providing a reliable infrastructure might foster successful tablet implementation.

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KEYWORDS

tablet PC; electronic health record; usability; health services; inpatient care

Introduction

An increasing average life expectancy paralleled by a declining birth rate has ushered in a constant demographic change in industrialized nations [1]. These processes have significantly affected health care service providers. In Germany, the most tangible consequences of the aging population are a 28% increase of cases treated in hospitals since 1991 [2] and a 46% decrease in length of stay per patient [3]. Within the same period, hospitals have registered a dramatic increase in the inpatient treatment of patients aged 50 years or older [2]. Clear evidence indicates that the number of diagnoses per patient ascends with age [4], meaning that older patients often require more extensive and costly treatment than the younger population [5]. As a direct consequence, expenditures for health state insurance in Germany rose by approximately 30% over the last decade [6]. Although experts expect this drift to progress, similar trends have been observed in other industrialized countries [7].

As a result, health care service providers find themselves in a position where they have to maintain good quality of services while dealing with sicker patients that often require more complex, and more time-consuming, treatment and diagnostic procedures. The clinical routine has thus become denser and involves handling larger amounts of data in less time. This underpins the need to optimize data handling within the clinical environment to enhance practitioners' efficiency. In addition, a growing gap in physician supply has been forecasted for at least one other Western nation [8]. This further highlights the need for streamlining clinical workflow. In line with this notion, physicians at German hospitals spend up to one-third of their average daily labor time on clinical documentation [9]. Therefore, this area in particular may benefit from workflow enhancements. Recent research provides solid evidence that quality and efficiency of health care delivery can be improved through the use of digital information systems [10]. Hence, it is unsurprising that many hospitals have already replaced traditional paper charts with electronic information systems to grant more efficient and less time-consuming data handling [11]. A solid base of evidence indicates that electronic medical records (EMRs) yield both process and structural benefits [12]. They can further promote availability of and access to patient data [13], which is of great importance considering that access to these data is often crucial in making medical decisions [14]. Although mobile EMRs provide location-independent access to patient data in real time [15], it has been asserted that modern tablet PCs may be appropriate hardware in this context [16]. Recent research suggests that such devices possess several features that make them particularly suitable for the clinical environment. These include large screens that offer convenient access to graphical content, long battery life, a high degree of portability, and sufficient storage capacity [17]. Positive patient attitude toward tablet use by doctors [18], easy disinfection, and the availability of a broad selection of medical apps make the devices even more attractive for professional use within medical settings [16]. In summary, tablets unarguably offer an appealing potential for clinical use.

However, until recently there were no studies investigating the impact of tablets with EMRs on the clinical routine within an inpatient setting. In a first attempt to shed light on this current issue, we conducted a study that aimed to examine potential benefits of tablets with mobile EMRs on a hospital ward [19]. In this context, we explored quantitative effects of tablet use as an extension of the established gold standard (paper chart and trolley with laptop running an EMR) on labor time in comparison to exclusive use of the existing gold standard. Results showed that tablet use led to significant time savings during the preparation and postprocessing of ward rounds. We also found that checking a medical record was significantly faster in the presence of a tablet, which in turn led to a significant increase in doctor's time spent at the bedside. Yet, the underlying mechanisms of the obtained time savings remained unclear.

In addition to quantitative improvements as outlined previously, early qualitative studies report high degrees of satisfaction with mobile clinical information systems among physicians [20]. However, these studies were conducted before the tablet PC era. Research investigating physicians' perceptions of tablets in the clinical environment thus remains sparse. Anderson et al [16] examined physicians' perception of tablets in private practice settings. They found that physicians responded generally positively to the devices. Findings from a second qualitative study that was conducted in an emergency department suggest that tablet use can potentially streamline clinical workflow and improve physician-patient interaction [21]. These results are promising overall. However, none of these studies were conducted within an inpatient setting and, importantly, subjective reports (eg, through questionnaires) were rarely correlated with changes in objective measures. In order to fill this gap in the literature and to better understand the underlying causes for the significant time savings observed in our previous study [19], we gathered data through semistructured questionnaires. We further electronically tracked patterns of tablet use by participating physicians to gain a better understanding of how the tablets were utilized during the clinical work day. Our aim was to get a clear grasp of what features exactly were perceived as beneficial by physicians.

Methods

Participants

The study was conducted at the department of neurology at the Charité University Hospital in Berlin. Nine resident (2 female, 7 male) and five staff neurologists (all male) participated in the study. Two participants were younger than 30 years of age, seven were aged between 30 and 39 years, four were aged between 40 and 49 years, and one was older than 50 years. The main sampling criterion was to select physicians who regularly engaged with the clinical routine. This criterion was met by all participants. Physicians were informed that they would be required to provide feedback regarding their practical experience with the tablets following the study period. A total of five participants agreed to participate in the electronic data tracking. All participants gave informed verbal consent before completing the questionnaire. No information regarding hypotheses was disclosed at this point. Data collection was fully confidential. Participants were told not to use their tablet in case they felt

that this would hinder the delivery of health service in any conceivable sense (eg, in the case of an emergency). Participants were free to withdraw from the study at any point. However, none of the participants withdrew. The study received approval from the Ethical Review Board of the Charité Teaching Hospital, Berlin, and was conducted in accordance with the Helsinki Declaration.

Design

This study aimed to explain effects of tablet use on the clinical routine that were observed in a previous study. It is beyond the scope of this paper to provide full details regarding the study design (please refer to [19]). In brief summary, the study was conducted within groups with one interventional and one control condition. The intervention consisted of tablets equipped with EMRs that were used in addition to the existing information system. The latter comprised a conventional paper chart and a ward trolley with a laptop running a desktop version of the EMR. We employed a crossover design. Tablet use was for a period of 7 weeks in total for all participants. Following the study period, physicians were administered questionnaires. They were instructed to anonymously complete and return the questionnaires within the space of 1 week by dropping them into one of the researcher's postbox. This was done to ensure full confidentiality of data collection. Five of the devices used in this study electronically collected usage data from participants. Tracking data were automatically captured and subsequently stored on the device.

Tablets

This study used iPads (iPad mini, Apple Inc, Cupertino, CA, USA) running a mobile EMR (SAP EMR Unwired Version 1.10, SAP AG, Walldorf, Germany). Main features of the software included information regarding ward usage, diagnoses, functional diagnostics, risk factors, laboratory and imaging results, clinical order status, and patient demographics in realtime. Vital signs and medication data remained paper bound in both conditions. Clinical tasks and progress notes could be entered and shared with the backend system. However, physicians were unable to enter clinical orders through the tablet. Although tablets were enabled to connect with the Internet, camera use, the screenshot function, and cloud service use were not available. Physicians were only allowed to install apps if these met data protection requirements as defined by the information technology department. For data protection, patient data were not stored on tablets at any time during the study. Instead, data were saved to a backend that could be accessed through the tablet's frontend. To access patient data, users had to enter a six-digit alphanumeric code to deactivate the key lock on the tablet. The key lock switched on automatically when the tablets remained unused for more than 5 minutes. The EMR sessions timed out after 2 minutes. A second password was required to access the software.

Participants' patterns of use within the EMR environment were electronically tracked and automatically stored through the iOS debug mode. Following the study period, usage records were downloaded from the tablets and stored on a computer. The data on the devices were deleted following data transfer. For full confidentiality, the procedure did not allow for establishing a link between user names and datasets.

Questionnaires

We constructed a survey questionnaire that aimed to examine users' perceptions of and attitudes toward tablets with mobile EMRs during the workday. Before administering the questionnaire, content validation was obtained through a preliminary study with three physicians. Following a thorough revision process, the questionnaire was modified for clarity. Physicians who had participated in the preliminary study were excluded from subsequent data collection. The questionnaire contained a total of 57 items including six categorical, five open-ended, and 46 5-point Likert scale questions. To control for data validity, 30 items were reverse scored. We used traditional 5-point Likert scales throughout the questionnaire. Scale levels were designed as follows. For normally scored items, 1 indicated a clear improvement, 2 reflected a moderate improvement, whereas 3 indicated no detectable effects. Accordingly, 4 and 5 reflected a moderate or clear change for the worse, respectively. For reverse-scored items, an inverse order of ratings applied (1=clear change for the worse, 5=clear improvement). Physicians were explicitly asked to respond to questions regarding work processes that involved tablet use and to provide feedback on how the tablets impacted their clinical routine (eg, Location-independent data access improved the doctor-patient interaction. 1=strongly disagree; 2=disagree; 3=neutral; 4=agree; 5=strongly agree).They were also asked to state their attitudes toward the tablets (eg, What is your favorite documentation tool during ward rounds? 1=paper chart; 2=ward trolley with laptop; 3=tablet). Response scales were designed to specifically comprise different dimensions of tablet use, including perceived overall efficiency of the tablet, satisfaction of data retrieval with the tablet, and general satisfaction with the device. The questionnaire also required participants to provide basic demographic data such as age, occupational group, attitude toward novel technologies, and gender. Open-ended questions provided the opportunity for physicians to leave individual comments of a more general nature (eg, Are there any further aspects in the context of tablet use that you would like to comment on?). A copy of the questionnaire is provided in Multimedia Appendix 1.

Statistics

All quantitative data analyses were carried out using SPSS Statistics version 22 (IBM Corp, Armonk, NY, USA). Confidence intervals for 5-point Likert scales were calculated through a bootstrap resampling procedure. A nonoverlap of 95% confidence intervals between the sample's mean and the mean value of the response scale indicated a significant finding. Also, a sample's mean value was, by definition, significantly different from any single value if the single value was not included in the confidence interval. For example, if one used a 5-point Likert response scale with the response options 1=much better, 2=better, 3=neutral, 4=worse, and 5=much worse to test whether graphical content was better accessible through tablets than via common computers, then any confidence interval with a lower and an upper margin below the mean value of the scale "3" would indicate a significant finding (eg, 95% CI 2.23-2.84)

in favor of the tablet. However, any overlap with the mean value (eg, 95% CI 2.81-3.42) would indicate a nonsignificant finding, whereas any confidence interval with a lower and an upper margin greater than 3 would significantly indicate that graphical content was more conveniently accessed through common PCs. We chose this specific procedure because bootstrapping provides more detailed statistical information than *P* values [22]. Limited space required a careful selection of which questionnaire items to include in this section. Thus, we decided to only include significant findings at this point. Means are reported along with the upper and lower margin of their 95% confidence interval. Reverse-scored items are indicated as such.

We further ran a multivariate analysis to identify factors that predicted physicians' satisfaction with the tablets. Outcome variables used in this context were "preferred way of documentation," "motivation regarding future tablet use," "did the tablet pose a useful extension to the current gold standard," and "overall satisfaction with the tablet."

Tracking data were analyzed using Matlab (MATLAB 2008b, Mathworks, Natick, MA, USA). Tablet functions were automatically pooled in categories (eg, reports from diagnostic procedures such as ultrasound and electrophysiology were categorized as "documents"). We then analyzed the access frequencies for each category.

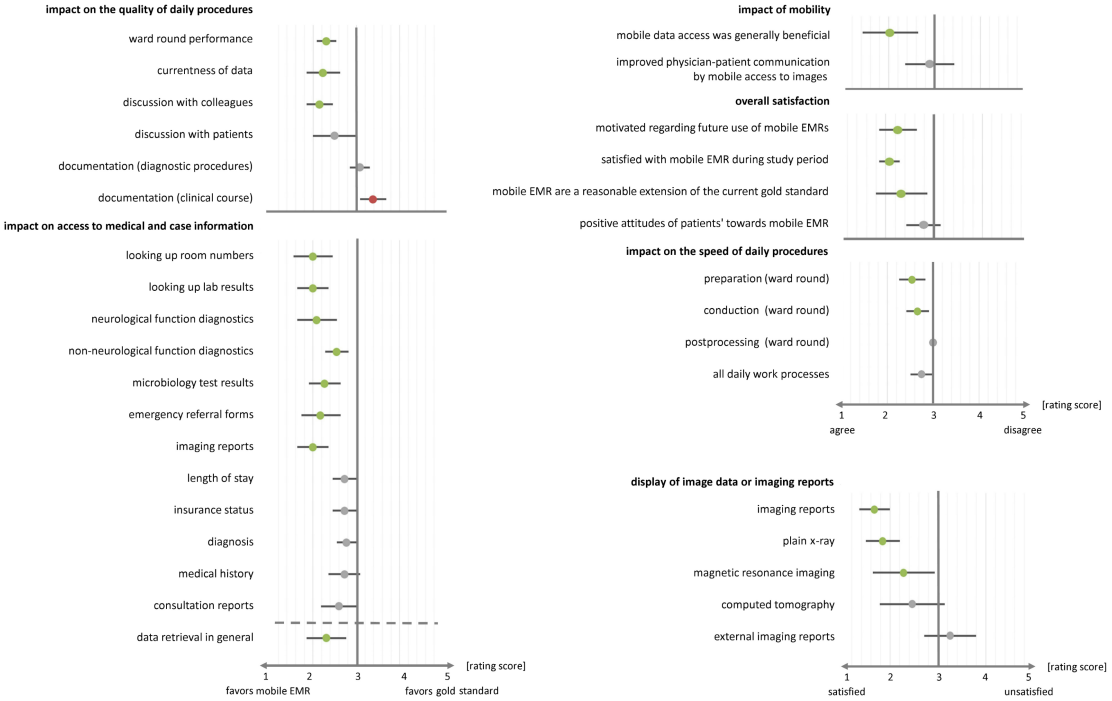
Results

Survey Questionnaire

All participants completed and returned the questionnaires, resulting in a total of 14 datasets that were included in the final analysis (see Figure 1 for a graphical summary of results). Bootstrapping indicated that participants perceived data retrieval to be accelerated through tablet use (mean 2.31, 95% CI 1.85-2.77). More specifically, they felt that looking up patient's room numbers (mean 4.00, 95% CI 3.55-4.45, reverse ordered), laboratory results (mean 4.00, 95% CI 3.64-4.36, reverse ordered), neurological function diagnostics (mean 3.91, 95% CI 3.45-4.36, reverse ordered), microbiology (mean 3.73, 95% CI 3.36-4.09, reverse ordered), emergency department referral forms (mean 3.82, 95% CI 3.36-4.27, reverse ordered), and other clinical evidence (mean 3.45, 95% CI 3.18-3.72, reverse ordered) required less time when using a tablet.

The retrieval of graphical material also received high ratings throughout the questionnaire. According to the participants' responses, x-rays (mean 4.00, 95% CI 3.64-4.36, reverse ordered), computed tomography images (mean 4.00, 95% CI 3.64-4.36, reverse ordered), and magnetic resonance imaging (MRI) images (mean 4.00, 95% CI 3.64-4.36, reverse ordered) were all accessed quicker through tablets. Physicians further reported high degrees of satisfaction with the way radiological evidence was presented on the tablet (mean 4.34, 95% CI 4.00-4.64, reverse ordered). Both x-rays (mean 4.14, 95% CI 3.79-4.50, reverse ordered) and MRI images (mean 3.79, 95% CI 3.07-4.36, reverse ordered) received significantly positive ratings. Tablet representation of clinical evidence without image data was also perceived as positive (mean 3.71, 95% CI 3.14-4.21, reverse ordered). Participants further felt that preparing (mean 2.26, 95% CI 2.31-2.85) and conducting (mean 2.69, 95% CI 2.46-2.92) ward rounds required less time with a tablet. They also stated that tablet use streamlined clinical workflow when carrying out ward rounds (mean 2.31, 95% CI 2.08-2.54). Furthermore, physicians reported improvements when discussing clinical evidence with colleagues (mean 2.23, 95% CI 1.85-2.62) and patients (mean 2.15, 95% CI 1.85-2.46) due to tablet use. Another perceived benefit of the tablet consisted in location-independent up-to-date access to patient data (mean 4.00, 95% CI 3.36-4.57, reverse ordered). Results further indicated that tablet use was generally viewed as a useful extension of the current gold standard (mean 2.29, 95% CI 1.79-2.86). Physicians showed high degrees of motivation to use tablets during future ward rounds (mean 2.21, 95% CI 1.86-2.64).

Figure 1. Summary of the survey data representing mean values of participants' responses (dots) along with their 95% confidence intervals (bars). Colored dots: statistically significant at α=.05; gray dots: nonsignificant result; green dots: improvement through tablet use; red dots: no improvement through tablet use.



Subjective Time Savings

Average estimates of the tablet's effect on time required to carry out clinical work processes were as follows. Participants felt that time savings during preparing (4.8 minutes), conducting (6.5 minutes), and postprocessing ward rounds (0.8 minutes) were achieved through tablet use. They further estimated that data retrieval via tablet saved approximately 9.6 minutes per workday.

Open Questions

Six participants stated that the opportunity to enter clinical orders directly through the tablet would pose a desirable additional feature. Yet tablets in our study did not provide this function. Five participants stated that discharge reports should be accessible via tablet. Two participants criticized the time-consuming log-in procedure. Further comments included a positive feedback regarding tablet size and the suggestion to make the camera function available for clinical use (eg, to monitor muscle atrophy).

Further Items

The question: "What documentation tool(s) do you prefer during ward rounds?" yielded the following responses: trolley with laptop plus tablet (n=2), tablet (n=3), paper chart plus trolley with laptop (n=2), and trolley with laptop (n=1). One participant stated that he or she had no clear preference, whereas two participants did not answer the question.

Predictors for Tablet Use

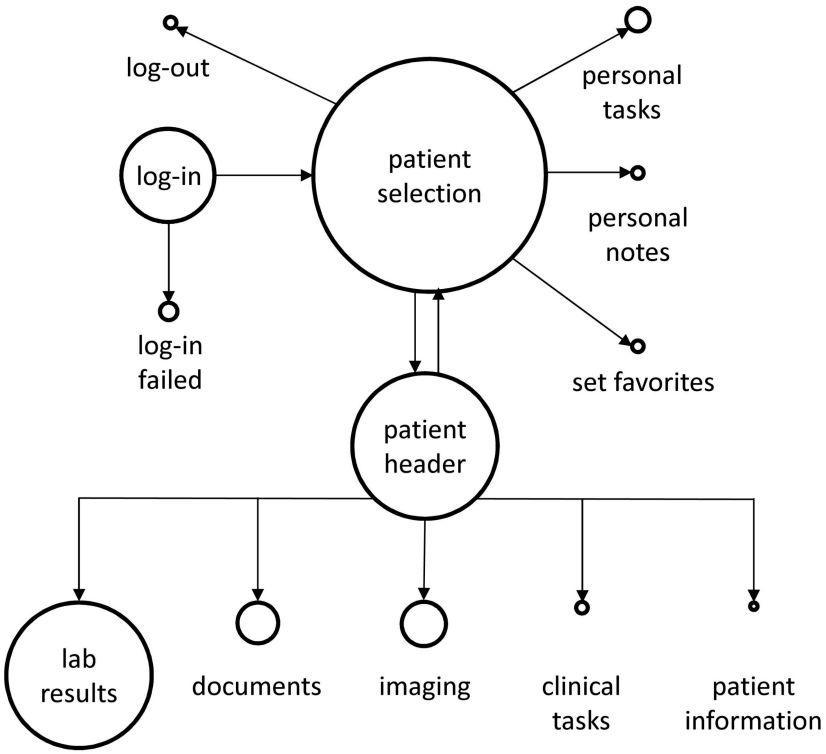
Demographic data showed 10 participants were interested in novel technologies, whereas four participants stated that they were not concerned with novel technologies. A multivariate analysis yielded that interest in novel technologies ($F_{1,11}$=7.17, P=.04) posed a positive predictor regarding participants' perceptions of the tablet as a useful extension to the established medical information system. The variable occupational group ($F_{1,11}$=10.54, P=.02) was also a significant predictor in this context with residents rating the device more positively than consultants. The variable age (P=.21) did not significantly impact on the outcome variable "did the tablet pose a useful extension to the current gold standard," but it was a predictor of motivation regarding further use ($F_{3,11}$=3.54, P=.04) with physicians younger than 40 years of age showing higher motivation. However, none of the other predictors (ie, age, occupational group, interest in novel technologies) were significant regarding the preference for certain documentation tools, motivation for future tablet use, and overall satisfaction with devices.

Tracking Data

A total of 732 data points were collected through automatic electronic data capturing. Figure 2 displays an overview of the tracking data results. Log-ins failed in 16% (10/62) of the recorded cases. Log-outs were recorded for 6% (3/52) of the sessions only. The remainder of the sessions were logged out automatically after the session had timed out (94%, 49/52). In addition to the navigation, log-in, and log-out procedures, the most frequently accessed features were looking up laboratory results (38.9%, 98/252), imaging data (11.1%, 28/252), and function diagnostics (10.3%, 26/252). Functions that were rarely (<1%) used or not accessed at all included task interaction (eg, sending tasks to a colleague), checking the medical history, and using supplementary features such as drug information and the built-in Web browser. The remainder data points represented subfunctions within functions (eg, use of tools to display trends of laboratory results) and were thus not included in the analysis.

As Figure 2 illustrates, laboratory results, viewing documents, and imaging made up a large share of total use. Interactive tools designed to foster communication among doctors or to create personal notes were used less frequently. Specific software training may encourage users to exploit the full potential of these features. The figure also displays a high number of failed log-ins (approximately 15% of total software access).

Figure 2. Summary of electronic data tracking illustrating access frequencies of the software features. Only features that made up a minimum of 1% of total tablet use are displayed. Circle size represents proportional access frequencies of software features in relation to one another. Arrows show connections of software features within the electronic medical record menu.



Discussion

The aim of this study was to better understand physicians' attitudes toward and preferences for tablet use within an inpatient setting. To our best knowledge, this is the first study that investigated physicians' perception of tablets running an EMR in an inpatient environment and in the context of proven objective benefits [19]. Results indicate high degrees of satisfaction with the devices among physicians along with a strong motivation to use tablets in the future. Participants felt that tablets allowed for quicker access to patient data. They also valued the mobile access to patient data and were contended with the way data were presented on the tablet. In line with the literature (eg, [21]), physicians reported that tablet use improved physician-patient interaction and streamlined clinical workflow. The latter also became evident due to perceived time savings as a result of tablet use. A novel finding from this study was that tablet use also improved interaction between physicians.

Overall results from this study add on to the growing body of evidence indicating that physicians view tablets as clinically useful [16,21,23]. The survey also provides novel evidence for the perceived value of tablets within an inpatient setting. This finding is of great importance because previous studies only examined the issue within emergency departments [21,23] or at a rural practice [16]. However, we also found that novel features of mobile EMRs that extend functionality beyond that of classic paper charts or laptops were rarely exploited.

Underestimation of Objective Time Savings

In our study, physicians' positive perception of tablet use resulted largely from the device's potential to expand and improve access to medical data. One of the main perceived benefits was faster data retrieval through tablet use. This is in line with previous research suggesting that fast access to the required data plays a key role in enhancing physicians' motivation to use tablets [15]. At this point, however, it is important to note that subjectively perceived time savings in this study were largely congruent with objective time savings that were measured in the context of quantitative evaluations [19]. Although physicians estimated that tablet use saved approximately 10 minutes of time over the entire workday in connection with data retrieval, objective measurements yielded that physicians required approximately 1 minute less for checking a patient's medical record during ward rounds when using a tablet [19]. Given that physicians on the study ward saw approximately seven patients each during their daily ward round, these estimates appear to be somewhat precise.

However, physicians' estimates regarding time savings within the context of ward round duration were less accurate. Although they felt that tablet use saved only 4.8 minutes during preparation and 0.8 minutes during the postprocessing of ward

rounds, objective time records that were obtained through self-monitoring and direct observation indicated time savings of 20 minutes and 15 minutes, respectively (for full details, see [19]). Similarly, physicians' average estimate of conducting ward rounds differed substantially from the actual times; participants perceived time savings of 6.5 minutes per ward round, but the time required to carry out ward rounds remained unaffected by tablet use. However, it should be noted that conducting ward rounds was more effective in the presence of a tablet because time savings in the context of checking medical data led to prolonged patient-physician interaction. It remains unclear why physicians were misled in regards to perceived time savings. However, considering the tight schedule of the clinical routine, one obvious conclusion to draw from these results is that perceived time savings played a major role in enhancing physicians' motivation regarding future tablet use.

User Satisfaction

Another important insight provided by this study was the high degree of satisfaction among physicians with the way data were presented on the tablet. Previous research suggests that data presentation impacts significantly on physicians' motivation to use EMRs [15]; however, the previously mentioned finding offers an intuitive explanation about why physicians in this study felt that tablet use improved physician-patient interaction. Previous studies yielded that physicians value the quick and easy way to share medical information with patients as provided by tablets [16,21]. In accordance with these findings, results from our previous study showed that tablet use led to a mean increase of time spent at the bedside of 1 minute per patient encounter [19]. It is plausible that mobile data access encouraged physicians to share medical information over the device with patients, which may explain the increase in time physicians spent at the bedside. This may then have impacted positively on the physician-patient interaction because one determinant in patient satisfaction appears to be the amount of time patients spend with their physician [24].

Demand for Further Development

However, despite the largely positive feedback in the main aspects of this study, participants also highlighted some limitations of the tablets. In line with previous studies [16], there was a clear demand for additional apps and functions to further enhance the benefit of tablets. Particularly, our sample wanted the opportunity to enter clinical orders through the tablet and a simpler log-in procedure. The latter appears to be of greater practical relevance considering that tracking data revealed a large number of failed log-ins. Fingerprint log-in appears to be a suitable alternative in this context because this would grant an easy, less time-consuming log-in. There were also a large number of failed log-outs, which may spark security concerns regarding clinical tablet use at first sight. However, all participants were instructed to adhere to the strict code of data protection relevant in the context of this research project at all times. They were instructed not to leave tablets unattended at any point and to store devices in their coat pocket when not in use. The fact that the device remained in a safe place when unused provides a plausible explanation why physicians relied on the auto log-out function in the majority of the recorded cases, which made a manual log-out technically redundant. Further limitations are discussed subsequently.

Exploiting the Full Potential

The software provided a total of 68 functions. However, tracking data yielded that the physicians accessed only 15 functions frequently (more than five times during the study period). These predominantly included looking up medical evidence and especially laboratory results. Accordingly, feedback on this particular dimension was largely positive. The sparse use of tablets for clinical documentation might have been because appropriate functions were not fully available on the devices. The tablet's software lacked the opportunity to enter clinical orders. Although users could enter personal notes, it was not possible to edit these or to delete outdated notes on the device once they were saved to the system. This could only be done through a desktop workstation. In addition, users might have perceived it as difficult to enter information via a digital keyboard. Therefore, they may have preferred the physical keyboard provided by the laptop that was available throughout the study for a more common keyboard experience. It appears plausible that such shortcomings might have impeded users' motivation to use the tablet for documentation purposes, leading to a mainly negative perception of the device in this regard. Functions that were also rarely used included the opportunity to create notes and to share these with colleagues. Yet users did not provide feedback on why they neglected these functions. Feedback regarding unused functions was neutral throughout; therefore, one plausible explanation is that participants were unaware of these functions or their potential. Comprehensive training sessions including practical examples might help physicians to explore the full potential of the tablets.

Limitations

One obvious limitation of this study is the fact that the physicians were free to return to the gold standard whenever they wanted to. Therefore, it cannot be ruled out that tablet use was restricted to occasions when the physicians felt that it would be convenient to use the device. Hence, the study design does not allow us to draw conclusions about whether tablets have the potential to replace the current medical information system. We can only establish that tablets were perceived as a helpful extension to the current gold standard.

Another limitation was the restricted scope of the available functions. In the context of our study, physicians primarily used the tablet as a mobile information system. Thus, it remains unclear how physicians would have reacted to the device if they had the opportunity to enter clinical orders via the tablet.

This study was also limited by the fact that the degree of practical work varied among participants. More specifically, our sample represented a range of user behaviors depending on the occupational group. Therefore, results provide only limited insight into the specific requirements of distinct user subgroups. Finally, this study was conducted at a single institution with a limited number of participants and results from this study might not generalize to other hospitals and other medical disciplines (conservative vs surgical).

Conclusion and Perspective

This is the first survey providing evidence that physicians perceive the use of tablets as clinically useful within an inpatient setting. These findings may have potentially wide-ranging implications. High degrees of motivation to further use tablets among physicians along with well-documented time savings as a result of tablet use during the clinical routine constitute promising preconditions for further clinical use of the devices. Software improvements and comprehensive training sessions on the device appear necessary to encourage users to exploit the full potential of the tablets. However, to gain a more profound understanding of the tablet's potential benefits, further studies at different institutions involving health care professionals from disciplines other than neurology will be necessary. In this context, future research should also aim to investigate how physicians respond to tablets as documentation tools.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Survey questionnaire appendix.

[PDF File (Adobe PDF File), 59KB - mhealth_v4i2e70_app1.pdf]

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Abbreviations

EMR: electronic medical record
MRI: magnetic resonance imaging

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Original Paper

Designing, Implementing, and Evaluating Mobile Health Technologies for Managing Chronic Conditions in Older Adults: A Scoping Review

Nancy Matthew-Maich[1,2], RN, PhD, MSc(T); Lauren Harris[3], MSc(OT)Reg, BSc.; Jenny Ploeg[2], RN, PhD, MScN; Maureen Markle-Reid[2], RN, PhD, MScN; Ruta Valaitis[2], RN, PhD, MScN; Sarah Ibrahim[4], RN, MN; Amiram Gafni[5], PhD; Sandra Isaacs[2], RN, PhD

[1]Aging, Community & Health Research Unit, McMaster University, Mohawk College/McMaster University School of Nursing, Hamilton, ON, Canada

[2]Aging, Community & Health Research Unit (ACHRU), School of Nursing, McMaster University, Hamilton, ON, Canada

[3]SickKids Hospital, mHealth Innovation, Toronto, ON, Canada

[4]Arthur Labatt Family School of Nursing, Department of Nursing, Western University, London, ON, Canada

[5]Aging, Community & Health Research Unit (ACHRU), Clinical Epidemiology and Biostatistics (CE&B), McMaster University, Hamilton, ON, Canada

Corresponding Author:
Nancy Matthew-Maich, RN, PhD, MSc(T)
Aging, Community & Health Research Unit, McMaster University
Mohawk College/McMaster University School of Nursing
#354 McMaster-Mohawk Institute for Applied Health Sciences
1400 Main Street West
Hamilton, ON, L8S 1C7
Canada
Phone: 1 9055404247 ext 26793
Fax: 1 905 528 8242
Email: nancy.maich@mohawkcollege.ca

Abstract

Background: The current landscape of a rapidly aging population accompanied by multiple chronic conditions presents numerous challenges to optimally support the complex needs of this group. Mobile health (mHealth) technologies have shown promise in supporting older persons to manage chronic conditions; however, there remains a dearth of evidence-informed guidance to develop such innovations.

Objectives: The purpose of this study was to conduct a scoping review of current practices and recommendations for designing, implementing, and evaluating mHealth technologies to support the management of chronic conditions in community-dwelling older adults.

Methods: A 5-stage scoping review methodology was used to map the relevant literature published between January 2005 and March 2015 as follows: (1) identified the research question, (2) identified relevant studies, (3) selected relevant studies for review, (4) charted data from selected literature, and (5) summarized and reported results. Electronic searches were conducted in 5 databases. In addition, hand searches of reference lists and a key journal were completed. Inclusion criteria were research and nonresearch papers focused on mHealth technologies designed for use by community-living older adults with at least one chronic condition, or health care providers or informal caregivers providing care in the home and community setting. Two reviewers independently identified articles for review and extracted data.

Results: We identified 42 articles that met the inclusion criteria. Of these, described innovations focused on older adults with specific chronic conditions (n=17), chronic conditions in general (n=6), or older adults in general or those receiving homecare services (n=18). Most of the mHealth solutions described were designed for use by both patients and health care providers or health care providers only. Thematic categories identified included the following: (1) practices and considerations when designing mHealth technologies; (2) factors that support/hinder feasibility, acceptability, and usability of mHealth technologies; and (3) approaches or methods for evaluating mHealth technologies.

Conclusions: There is limited yet increasing use of mHealth technologies in home health care for older adults. A user-centered, collaborative, interdisciplinary approach to enhance feasibility, acceptability, and usability of mHealth innovations is imperative.

Creating teams with the required pools of expertise and insight regarding needs is critical. The cyclical, iterative process of developing mHealth innovations needs to be viewed as a whole with supportive theoretical frameworks. Many barriers to implementation and sustainability have limited the number of successful, evidence-based mHealth solutions beyond the pilot or feasibility stage. The science of implementation of mHealth technologies in home-based care for older adults and self-management of chronic conditions are important areas for further research. Additionally, changing needs as cohorts and technologies advance are important considerations. Lessons learned from the data and important implications for practice, policy, and research are discussed to inform the future development of innovations.

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KEYWORDS

Telemedicine; Mobile health; Health Plan Implementations; Evaluation Studies as Topic; Design; mHealth Innovations; Frail Elderly; Older Adults; Multiple Chronic Conditions; Home Care Services; Scoping Review; Communication; Information Communication Technologies

Introduction

As developed countries' populations age and associated chronic health conditions increase, alternatives to hospital and institutional care are needed. The United Nations estimated that by 2050, the world population of older adults over 60 years will have doubled, while the age group over 80 will have tripled from 2013 statistics [1]. In 2013, seniors represented 15.3% of Canada's population; by 2056, one quarter of Canada's population will be over 65 years of age [2]. Interest in supporting older adults with chronic conditions to stay in their own homes rather than move to institutions has increased [3]. Consequently, understanding whether mobile health (mHealth) technologies can help to support older adults stay in their homes through improved self-management and increased home care provider efficiency is a priority area of policy development. Given continuous improvements in technologies, it makes sense that mHealth may enhance health care delivery by improving dimensions such as communication, collaboration, and use of evidence-based guidelines for care of older adults with chronic conditions. Although mHealth and technology innovations are rapidly developing, research to guide practice and policy in this arena is still in its infancy. The purpose of this paper is to present a scoping review of the literature pertaining to mHealth solutions intended to address the needs of older adults living at home with chronic conditions. This paper will add further insight into best practices for designing, implementing, and evaluating mHealth solutions for older adults living in their homes and those who care for them (professional and informal caregivers).

It is estimated that approximately one in four older adults have two or more chronic conditions and half of older adults (≥ 65 years) have three or more (ie, heart disease, diabetes, arthritis, chronic lower respiratory tract disease, stroke, chronic obstructive pulmonary disease [COPD], dementia, and hypertension) [4-9]. To manage chronic conditions more effectively, researchers and policy makers have promoted patient and family-centered home-based health care, founded on interprofessional and community-based partnerships [10-15]. Consequently, there is a push to incorporate novel ideas for empowering older adults and their caregivers to manage their own conditions and to foster communication among the circle of care [16-19].

The field of mHealth, as defined by the World Health Organization (WHO) [20] is the "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices" (p. 6). The growing appeal of mobile solutions for health promotion and health care delivery can be attributed in part to the accessibility of the technology, the level of personalization that technology enables, valuable location-based services, and timely access to information through data, voice, and/or video media [21]. Several studies have piloted mHealth interventions for managing chronic conditions such as diabetes [22-25], COPD [26-28], Alzheimer's/dementia [29-31], and osteoarthritis [32,33]. Findings from these studies indicate that the use of mHealth interventions has the potential to support successful management of chronic conditions and health behavior change in the areas and systems studied through the following: (1) improving patient self-monitoring and management [34,35], (2) building social networks for patients [36,37], (3) informing health care professionals of patients' health status [37,36], (4) providing indirect feedback interactions [38,39], (5) tailoring care and education to patient needs [40-42], and (6) improving communication among health care professionals [43,44]. It is anticipated that this list will perpetually expand considering the recent momentum of mHealth innovation.

Despite these promising opportunities, the current literature supporting the use of mHealth primarily includes pilot and/or feasibility studies [45]. Large-scale trials and information on best practices for the design, implementation, and evaluation of such technology are limited. A recent survey by the WHO found that only 12% of member states reported evaluating mHealth services and that little was known about how to effectively evaluate such solutions [20]. Concerns related to data security, technology literacy levels of potential end-users, and other key issues highlight the importance of considering the overall architecture of the mHealth system and the context in which it will be used. As a result, there is a need for evidence to inform the successful research and development of mHealth solutions and to garner an improved understanding of the key elements and fundamental components of designing, implementing, and evaluating successful mHealth applications for managing chronic conditions associated with a community-dwelling aging population [20,46]. A scoping review of the literature is presented as a fundamental first step to

understanding the current practices, state of knowledge, and evidence to inform future directions. As per the convention in conducting scoping reviews [47], this paper does not systematically evaluate the methodological rigor of included studies.

Methods

Study Design

The purpose of scoping reviews includes comprehensively synthesizing evidence to map a broad, complex, or emerging field of study and to identify gaps with the intent to inform practice, policy, and future research [47]. A scoping review methodology was chosen as a tool for systematically mapping and disseminating the breadth of research available to address the broad, complex, and novel research question, "What are the current practices and recommendations for designing, implementing, and evaluating mHealth solutions to support older adults with chronic conditions living in their homes?" More specifically, this review considers solutions that enable care-related communication, information sharing, and information access for older adults and those involved in the care of older adults with chronic conditions living in their homes. This includes technologies intended for use by health care providers (HCPs), family, significant others, and friends involved in care, as well as older adults themselves. HCPs include all health professionals as well as unregulated providers such as personal support workers. This review, as is appropriate with a scoping review methodology, encompasses a broad range of study designs and varied contexts including different countries, communities, technologies, implementation milieus, and chronic conditions/stages without separating those with single conditions from those with multiple chronic conditions.

To complete this scoping review, we followed the five-stage framework developed by Arskey and O'Malley [47] and further defined by Levac, Colquhoun, and O'Brien [48]. The stages include: (1) identification of the research question, (2) identification of relevant studies, (3) selection of relevant studies for the review, (4) charting information and data from the selected literature, and (5) summarizing and reporting the results of the review.

Identification of the Research Question

The research question was identified from a preliminary scan of the literature and drawing on the expertise of the research team and several stakeholders. Rationale for the question arose from the lack of existing consensus in the academic literature on designing, implementing, and evaluating mHealth solutions in community-based settings, specifically as it pertains to older adults living at home with chronic conditions.

Identification of Relevant Articles

The team collaboratively planned and implemented a search strategy to identify relevant literature that was specific to mHealth solutions targeting chronic conditions and community-based care of older adults. Keywords and related subject headings were identified in consultation with research librarians in order to capture a comprehensive list of potential sources. Keywords were identified and combined to address three components of the research question: (1) mobile or electronic devices, (2) technology-based health care delivery, and (3) an aging population and/or chronic conditions (Textbox 1). Keywords were searched using Boolean operators. The databases used to locate the relevant literature were the following: Cochrane Library, Embase, PsychInfo, Medline, and CINAHL. Databases were searched for English language articles published between January 2005 and March 2015. In addition, reference lists were searched and a key journal hand search was completed (Journal of Medical Internet Research). Only articles published in peer-reviewed scientific journals were considered for review.

Textbox 1. Scoping review keyword search strategy

Mobile/Electronic Device

- Cellular Phone, Mobile Phone, PDA, Smartphone, Tablet

Mobile Health/Telehealth

- Computer interface, Design, eHealth, Human factors, Implementation, Integration, mHealth, Mobile Health, Telecare, Telecommunication, Telehealth, Telemedicine, Usability, User-centred design, User-friendly

Condition/Population

- Cerebrovascular Accident, Chronic Disease, Community, Disease Management, Health Program, Health Service, Healthcare Delivery, Home care, Inter-professional, Point-of-care, Quality of Life, Rehabilitation, Rehabilitation Care, Reintegration, Stroke

Selection of Relevant Articles for the Review

Two reviewers independently searched the titles and abstracts of the retrieved literature. Conflicts were resolved by a third reviewer and through team consensus. Inclusion criteria were mHealth technologies focusing on at least one of the following: (1) chronic conditions associated with aging populations, (2) HCPs providing home care, and/or (3) older adults living at home and/or their informal caregivers. Research articles using different methodologies (qualitative, quantitative, and systematic reviews) as well as theoretical papers were included and all papers had to be in English. The exclusion criteria were the following: (1) mHealth solutions being used for diagnostics/imaging, acute care, body and environment monitoring or support devices, or robotics; (2) technology pertaining to healthcare in developing countries; and (3) non-English language publications. Methodological quality of the published articles was not a criterion for exclusion/inclusion.

This enabled the inclusion of a breadth of knowledge pertaining to the research question, as is consistent with scoping review practices [47-49].

Articles that potentially met inclusion criteria through abstract review were reviewed in full by team members. Meetings were held regularly to discuss reviewers' decisions specific to the inclusion and/or exclusion of articles. Both inclusion and exclusion criteria were revised as the search evolved, in order to best address the research question. Under the final revised criteria, only articles pertaining to older adults (>50 years old) with one or more chronic conditions living in their homes were included.

Charting, Summarizing, and Reporting the Results of the Review

A descriptive-analytical narrative method was used to extract and chart the data from the selected articles [47-49]. Using the same process of team consultation, data from the selected articles were first extracted onto a data charting form developed by the research team using an iterative process. Charts were used to collate, summarize, and share data for team review and decision making. Data entered included the following: authors, year of publication, purpose of the paper/study and innovation, study location and context (setting, end-users of innovation), study design, outcomes measured, main findings, and lessons learned. A coding scheme (framework) was created under four thematic categories: (1) design and development, (2) implementation, (3) evaluation, and (4) risks and benefits. Full articles were imported as pdf files into NVivo 10, a software program for qualitative analysis, for more detailed data extraction and coding. The authors applied the coding scheme to all pertinent text, and then further coded the data under emergent themes using an iterative process.

Results

Selection and Characteristics of Source Documents

In total, 1021 published articles were identified in the database search (Figure 1) and of these, 811 were excluded based on a review of titles and abstracts. Of the remaining 210, another 183 including 29 duplicates were excluded through independent review followed by team reviewer consensus, leaving a total of 27 articles. Ten more articles found through reference list reviews plus 5 articles found through a manual search of a key journal (Journal of Medical Internet Research) were accepted after applying inclusion/exclusion criteria. A total of 42 sources were included in this review.

Of the 42 studies included (Table 1), 9 were from the United States, 5 from Canada, 5 from the United Kingdom, 6 from Scandinavian countries (Denmark=3, Norway=1, Finland=1, Sweden=1), 3 from the Netherlands, 4 from Australia, 2 from New Zealand, 4 from East Asia (South Korea=1, Japan=1, Taiwan=2), and 1 each from China, Italy, Belgium, and Poland.

Seven of the selected articles were theoretical papers (discussion and position papers). Four were descriptive reports of existing interventions, and 3 were case studies describing processes of mHealth implementation. Two articles described predictive modeling techniques for screening patients in use of technology. Three qualitative descriptive studies elicited opinions concerning mHealth. There were 13 papers in which mHealth solutions were evaluated; 6 controlled trials, 3 mixed-methods studies, and 4 qualitative studies. Three studies were cross-sectional surveys, 3 were systematic or scoping reviews, 2 were methods papers, and 1 paper focused on simulation.

Of the 42 articles, 17 focused on older adults with single chronic conditions: diabetes (n=4), stroke (n=5), heart condition (n=4), COPD (n=1), and dementia or cognitive impairment (n=3). Six articles involved older adults with any chronic condition or multiple chronic conditions. Conditions were not specified in 18 articles, in some cases referencing older adults (n=5) or home care patients (n=6) and caregiver burden (n=1).

The majority of mHealth solutions described were designed for use by both patients and HCPs (n=19), followed by HCPs only (n=7), patients only (n=5), caregivers, patients, and HCPs (n=4), and patients and caregivers (n=3); one mHealth solution was targeted exclusively at family caregivers. The remaining 3 articles were nonspecific.

Table 1. Review article characteristics.

Article Location	Article Type[a]	Type of Article/ Study Design	Condition	Innovation	Innovation End-users
Alpay et al (2010) Netherlands [88]	1	Discussion paper	NS[b]	eHealth patient empowerment	Patients
Bujnowska-Fedak & Mastalerz-Migas (2015) Poland [82]	4	Cross-sectional survey	NS	Internet use for health by older adults	Patients
Barakat et al (2013) USA [67]	2	Qualitative descriptive	NS	eHealth competencies /HCP[c] workshop participants	HCP
Blake (2008) UK [90]	1	Discussion paper	Chronic disease	Mobile technology for monitoring & health promotion	Patients and HCP
Bosl et al (2013) USA [89]	2	Predictive modelling	NS	HCP screening for medication compliance at home	HCP
Boulos et al (2011) UK [53]	1	Discussion paper	NS	Mobile phones and app technology for mHealth	Caregivers, patients and HCP
Chan et al (2012) Australia [76]	2	Descriptive report	Diabetes	Web-based SMS[d] /mobile terminal	Patients and HCP
Chiang et al (2012) Taiwan [59]	3	Nonrandomized quasi- experimental design	Caregiver burden	Telemonitoring/phone counseling	Caregivers
Chumbler et al (2012) USA [84]	3	Single-blind RCT[e]	Stroke	Text messaging, phone, home visits	Patients and HCP
Cicolini et al (2014) Italy [56]	3	RCT	CVD[f]	Text messaging reminders	Patients and HCP
Dale et al (2014) New Zealand [77]	3	Mixed-methods survey; Pre-post test pilot	CVD	Mobile phone & Internet system	Patients and HCP
Eland-de-Kok et al (2011) Netherlands [91]	5	Systematic review	NS	eHeath vs usual home care	Patients and HCP
Esser & Goossens (2009) Netherlands [62]	1	Literature review/ theoretical	NS	User-centered design framework	Patients and HCP
Forducey et al (2012) USA [54]	3	Controlled trials (2 randomized, 1 not) (pilot studies)	Cognitive impairment	Telehealth: text messaging, videophone, phone	Caregivers, patients and HCP
Hall et al (2012) USA [78]	1	Discussion paper	NS	Telemedicine and mHealth for older adults	Patients
Hebert et al (2006) Canada [65]	1	Implementation decision framework	Diabetes and chronic diseases	Telecare implementation	Patients and HCP
Huang & Hsu (2014) Taiwan [58]	3	Qualitative pilot	NS	Social networking & telehealth; tablets	Caregivers, patients and HCP
Huijbregts et al (2009) Canada [85]	3	Mixed methods	Stroke	Telehealth delivery system	Patients and HCP
Joubert et al (2013) Australia [55]	5	Literature review	Stroke	Telestroke	Patients and HCP
Kim et al (2012) South Korea [42]	3	Quasi-experimental design intervention study	COPD[g]	uHealth devices (monitoring, education/home visiting)	Patients and HCP
Malinowsky et al (2014) Sweden [57]	3	Case control	Cognitive impairment	Tech screening tool	Patients
May et al (2011) UK [87]	2	Qualitative descriptive	Chronic disease	Telecare implementation	Caregivers, patients, and HCP /managers
McCullugh et al (2013) UK [51]	2	Case review	NS	Telehealth evaluation framework	Patients and HCP
Nielsen & Matthiassen (2013) Denmark [73]	2	Case study	NS	mHealth implementation and home care	NS

Article Location	Article Type[a]	Type of Article/ Study Design	Condition	Innovation	Innovation End-users
Nielsen & Mengiste (2014) Denmark [72]	2	Case study	NS	Mobile health diffusion (social world theory) and home care	NS
Nundy et al (2012) USA [52]	3	Qualitative descriptive pilot	Diabetes	Text messaging with follow-up	Patients and HCP
Nyborg et al (2013) Denmark [64]	2	Descriptive report	NS	Mobile phone for nurses and home care	HCP
Pandey et al (2013) USA [61]	4	Cross-sectional survey	Stroke	Mobile phones and app technology	Caregivers and patients
Paré et al (2011) Canada [74]	3	Mixed methods	NS	Laptop computer software and home care	HCP
Saywell et al (2012) New Zealand [79]	6	Study protocol/mixed methods	Stroke	Telerehab program	Patients and HCP
Stroulia et al (2012) Canada [50]	3	Qualitative/ ethnography	NS	Mobile ICT and home care	HCP
Townsend et al (2013) Canada [92]	2	Qualitative descriptive	Chronic conditions (multiple)	Ethics of eHealth	Caregivers and patients
Van Hoecke et al (2010) Belgium [75]	2	Descriptive report	Diabetes and multiple sclerosis	Web-desktop with PDA interface	Patients and HCP
Varnfield et al (2011) Australia [81]	2	Descriptive report	CVD cardiac rehab	Mobile phone and internet video conferencing	Patients and HCP
Varsi et al (2013) Norway [70]	3	Qualitative descriptive	NS	Internet patient provider communication service	Patients and HCP
Vuononvirta et al (2011) Finland [80]	2	Qualitative descriptive	NS	TeleHealth compatibility	HCP
Walters et al (2010) Australia [35]	6	Study protocol/RCT	CVD cardiac rehab	Mobile phone platform	Patients and HCP
Wang et al (2014) China [71]	5	Integrative review	Chronic disease	Mobile phone apps	Patients
Yellowlees (2005) USA [68]	1	Position paper/ theoretical	NS	Principles of successful telemedicine	NS
Zhang et al (2008) Japan [86]	6	Simulation testing	NS	Mobile phone & Internet; Teleconferencing and home care	HCP
Zhang et al (2014) UK [60]	2	Predictive modelling	Dementia	HCP screening for use of video streaming by patients	Patients and HCP
Zulman et al (2013) USA [83]	4	Cohort study - sample survey	Chronic conditions	mHealth technology for out-of-home caregiving	Caregivers and patients

[a]Type of Article: 1=theoretical, 2=descriptive, 3=intervention study, 4=population/cohort study, 5=review, 6=other

[b]NS: nonspecific

[c]HCP: health care providers

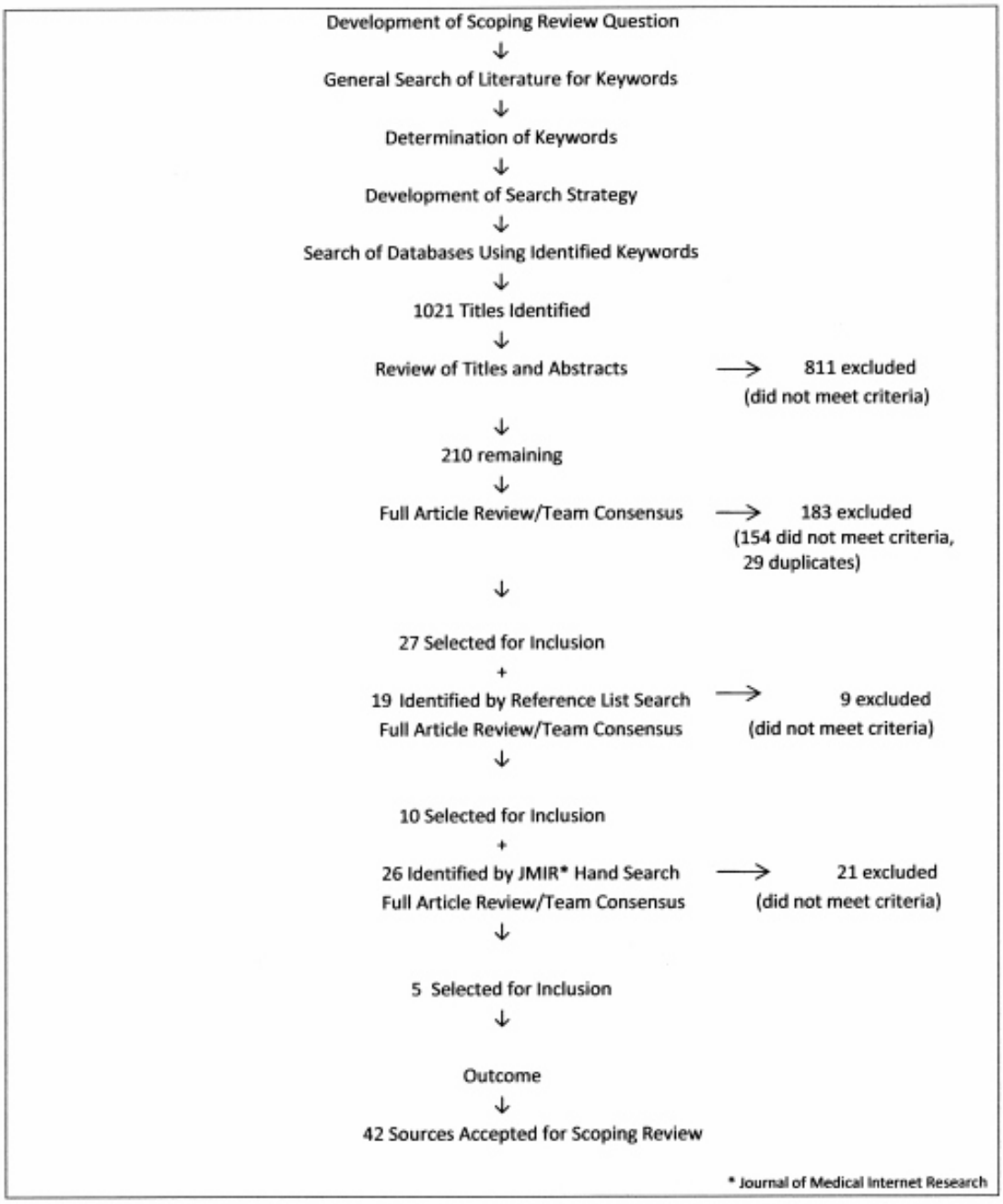
[d] SMS: short message service

[e]RCT: randomized controlled trial

[f]CVD: cardiovascular disease

[g]COPD: chronic obstructive pulmonary disease

Figure 1. Search strategy and results.



Review Findings

Results pertaining to mHealth solutions are organized under 3 phases of development: design, implementation, and evaluation. Given the iterative and cyclical nature of designing, implementing, and evaluating mHealth technologies, these categories are not discrete entities and inevitably overlap. The categorical terms were used to organize the review findings as commonly presented in the papers reviewed. Each section is discussed within thematic constructs derived from the analysis of the selected literature using an iterative process of qualitative content review.

Designing mHealth Solutions

Two thematic constructs emerged from the literature pertaining to practices and considerations in designing mHealth solutions: (1) user-centered design and (2) interdisciplinary/collaborative team approaches.

User-Centered Design

Recommendations from both research findings and theoretical perspectives are consistent regarding the need for end-user design. Multiple examples of end-user design approaches were provided within the literature [46,50-52]. End-user engagement throughout the design and development process guided researchers and developers in designing solutions to be acceptable, feasible, and sustainable by fitting within the end-user's context [48]. The user-centered approach allowed

researchers to obtain feedback from patients, caregivers, and HCPs who will be using the solution to address their specific needs and ideas, taking into account technology literacy and personal preferences [50,53-56]. Consideration of technological literacy and acceptance was particularly important when the mHealth solution involved older adults with cognitive impairment [56-58]. Attention to HCP aptitudes and preferences for technology as well as HCP value-based practices and adherence to patient-centered care were also deemed necessary [51,54,58]. Further, mHealth solutions are needed that address the health and information needs of informal caregivers related to their family member's well-being, with reassurances that health concerns are being managed [54,59-61]. Examples of design features solicited to support end-user needs and preferences are presented in Textbox 2.

Textbox 2. User-centered design features.

Software/App Features

- Graphs displaying patient-related trends (ie, glucose monitoring and medication) [58,75,89]
- Notification system, which alerts agencies, case managers, and professionals of specific patient responses that require attention and follow-up [52,75]
- Text messages (short message service, SMS), which contain motivational and educational information as well as reminders to improve treatment adherence in chronic diseases [35,71,81]
- Video messaging (patients with dementia) [60]
- Client management features: scheduling [75], patient record/information access [64,72,83], voice and text messaging [64,73]
- Aids for seniors: vision, hearing, memory [53]
- Patient texting features for reporting health status [76,85]

Hardware/Mobile Devices

- Mobile devices with large touch-screens and large virtual buttons (vs hard buttons) [53]
- Mobile phones not requiring end-users to reboot the system frequently; minimizing pop-ups; remote, seamless maintenance [53]
- Lighter tablets with a touch pen to suit the mobility of homecare providers [86]
- Voice input function [58]
- Cloud computing resources [58]
- Smartphones and voice-over-Internet protocol software applications (eg, Skype) [78]

Esser and Goossens [62] discuss the need for a user-centered design framework when designing mHealth solutions to meet the needs of an aging society, specifically through telemedicine. Their framework is derived from a review and consolidation of established frameworks used within the information and technology industry. The framework promotes patient-provider interaction as the starting point for design, acknowledging that "patient-provider consultation is considered to be the most complex, due to the interpersonal relationships that are involved" (p. 33). Other constructs incorporated into their model include technology acceptance and technology-mediated communication.

Interdisciplinary/Collaborative Team Approaches

Reviewed literature consistently reported the use of interdisciplinary team-based approaches in the process of designing and developing mHealth solutions. The interdisciplinary team in this literature consisted of technology experts and health care professionals as well as end-users and other affected stakeholders [46,51,52]. The literature identified the need for technical experts to work collaboratively in an iterative design process with patients, caregivers, health care professionals, and key stakeholders vested in health care delivery [51,53,63,64]. Collaborative practices enabled the documentation of a user-accepted yet technically feasible list of user requirements. One such example was the inclusion of features of minimal complexity for end-users, which were still based on the most advantageous and available technologies for designing solutions [51]. At the initial stage of design, Esser's user-centered design framework recognized the importance of three forms of input: individual, organizational, and technical context [62]. This latter statement supports the notion of multi-stakeholder/ multi-sectoral involvement as a means of ensuring different stakeholder interests are met [46].

In summary, continued engagement with end-users as well as collaborative team approaches that encourage multiple stakeholder involvement, are both essential in the successful design and development process for mHealth solutions. User-centered approaches enable researchers and engineers to prioritize an understanding of the context in which the solution will be used by a diverse group of end-users. It also helps to establish early on the specific app features and hardware considerations perceived to be acceptable, preferable, and compatible with the needs of the end-users. Integrating these features and hardware considerations throughout the design and development phase of the solution is imperative, as it influences end-users' response, engagement, uptake, and adherence. Collaboration among stakeholders ensures different interests are appreciated, and that knowledge transfer between content and technology experts is maximized.

Implementing mHealth Solutions

Three thematic constructs emerged from the literature pertaining to successfully implementing mHealth solutions: (1) feasibility in relation to organizational and systems readiness, (2) acceptability of the mHealth solution, and (3) usability in relation to the different end-users. These factors were reported to either facilitate or hinder the implementation of mHealth solutions.

Feasibility: Organizational and Systems Readiness

The need for health system readiness to adopt mHealth solutions was highlighted in much of the theoretical literature. At the institutional level, financial resources, policies, and workplace culture all play a key role in the successful adoption of mHealth technologies [46,65]. Organizational readiness for adoption was recognized as a multi-faceted and dynamic construct, essential for driving change [66]. Compared to most other industries, health care is relatively slow to adopt new technology and such resistance to change has likely contributed to the limited widespread adoption of mHealth solutions beyond the pilot phase [51,53,65,67]. The literature refers to the inertia and resistance to change that can exist within organizations [46,65], further highlighting the importance of a strategic business-focused plan for implementation [68]. The strategic plan needs to ensure sufficient, sustainable funding for the costs associated with implementing and maintaining the solution [46,52,67]. A look to business models for designing long-term management and support [68] could also inform research studies and development initiatives, currently limited in scalability beyond the pilot phase [46,69].

May et al reported how general uncertainties about policies and management systems were to blame for the lack of successful uptake of telecare services [46]. They argue for a systems perspective based on normalization process theory to ensure successful mHealth (telecare) implementation. In this approach, all stakeholders are involved during development and implementation to include the different end-user groups, as are suppliers/developers, policy makers, and health care managers. Further to this, Herbert et al proposed a decision framework when implementing telehealth solutions in chronic illness care, taking into account factors such as associated disease burden, health care patterns and resources, evidence of success, and overall readiness (management, service, and delivery) [65].

A lack of a clear reimbursement schedule was described as a barrier for clinicians to adopt mHealth technology [54,62,70]. A cohesive implementation team with clear leadership, ownership, and accountability was recommended to mitigate these uncertainties and facilitate acceptance by stakeholders. Further, choosing clinician champions who feel they have ownership of the system could effectively facilitate user acceptance within an organization [68]. Institutions were found to facilitate successful implementation by providing effective, ongoing technical and professional support to HCPs as end-users [71]. In the words of Yellowlees, “train, train, and train again” [68].

The process of adoption and diffusion of an mHealth solution was reported in a case review from Denmark [72]. Adoption of telehealth for community-dwelling older adults at a national level was reportedly triggered by demonstrated successes of a municipal project that simultaneously met the interests of major government stakeholders looking for fiscal efficiencies in health care delivery. The process was described as rapid diffusion accepted by government and then driven downward. With resistance felt at the micro level while local systems and the workforce adapted, the eventual target of full diffusion was reached after 10 years. The authors propose a social world perspective that offers an analysis of the politics of sociotechnical change applied at the macro (governance and finance), meso (manager), and micro (end-user) levels of experience. Their model speaks to differences in cultures and interests of different professional sectors, emphasizing the need for health care and technology to find a “common vocabulary” in order to enable successful mHealth implementation.

Acceptability of the mHealth Solution: The End-User Perspective

Delays in local adoption of mHealth technology were attributed to top-down approaches that neglect to address the impact on workload adjustments and practice preferences by the end-user workforce [72]. Not surprisingly, health care providers working in the community were more likely to adopt new technology if they saw benefits in terms of professional role support [67,72]. It was not uncommon for health care providers to report negative perceptions of the solution, specifically viewing it as a tool for organizational micromanagement [72,73]. This perception significantly reduced their willingness to adopt new technology. Generally, the mobile solution was accepted more by HCPs and patients when it had the capability to be customized to both the population of interest [74,75], and to individual preferences and response needs [52]. For example, when end-users associated automated alert messaging with responsive follow-up, they reported higher interest in engaging with the solution [52]. Studies have reported on the unique qualities of using mobile interfaces for health care purposes [58]; when information was found to be too complex to be read on a mobile screen, the information was not accessed effectively or at all [73].

Usability: User-Technology Interface

The perceived value and ease-of-use by the end-user was identified as a critical factor in successful adoption of an mHealth solution. End-user preferences and levels of technical literacy were felt to affect the way health care information is shared and accessed [57,67]. Generally, a solution will not be used if it is perceived to be “more trouble than it is worth” [67,72]. This was evident in situations where the solution was considered to be too time-consuming [76], unreliable [67], or generally burdensome (eg, multiple passwords to remember, difficulty with software installation) [58,77]. Solutions that are easily adoptable must fit naturally into the existing context, whether that means into the health care providers’ or patients’ existing daily workflow and routines [58,68] or integrating with other existing tools and applications [58,76,78]. For example, an application well received by end-users was developed using Facebook as the platform, enabling older adults and their family members to review health status information using familiar

social network technology, while HCPs were able to access selected information related to patient care [58].

In addition, special consideration must be given to the varied types of information that are shared via different mobile devices; mobile phones are limited in the amount of information that can fit on a screen compared to computers [53]. HCPs preferred larger computer screens over mobile devices for recording patient information [73]. From a patient perspective, tablets with touchscreens may be more accommodating for individuals with limited vision and dexterity, compared to mobile phones [58].

In summary, factors that support or hinder implementation of mHealth solutions include the following: (1) institutional environment such as culture, policies, and readiness to change; (2) the availability of a comprehensive business plan; (3) personal factors of the different end-users including perceived value of the mHealth solution; and (4) factors related to the solution itself, for example, ease-of-use by different types of end-users. These data highlight the importance of researchers understanding the culture, values, and readiness of different stakeholders and end-users from project inception, and also to continue to monitor and address end-user and stakeholder feedback.

Evaluating mHealth Solutions

A variety of quantitative, qualitative, and mixed-methods designs were used to evaluate mHealth solutions for older adults living at home. Researchers were interested in evaluating aspects of application design and implementation (eg, feasibility, acceptability, and usability), as well as health outcomes experienced by clients receiving the interventions (Table 2). Selected approaches used to evaluate mHealth solutions were grouped under 3 thematic constructs: (1) design and formative evaluation; (2) implementation, process, and outcome evaluation; and (3) frameworks for planning evaluation.

Table 2. Constructs measured in mHealth studies

Domain	Construct	Measurement Tools
End-User Perceptions: Acceptability & Feasibility	End-User Satisfaction	*Clients:* Written questionnaire survey post-intervention [35, 42, 77, 81, 86] Interviews [58, 79] Focus groups post-intervention [85] *HCPs:* Structured questionnaire survey post-intervention [74, 81] Focus Group [85] Semi-structured interviews [74] *Family caregivers:* Interviews [58]
	Usability	*Frequency of use and usage patterns:* Measured by built-in data analystics system[58, 81] *Ease of use:* Questionnaires [35] Interviews [58] Technology Usability Scale [57]
	Intervention Feasibility	Attendance/utilization rates [77,85] Focus group [85] Facilitator log [85]
Patient Health Outcomes	Quality of Life/Well-being	Reintegration to Normal Living Index [85] Functional Independence Measure (Telephone version; Motor subscale) [84] Late-life Function and Disability Instrument [84] Geriatric Depression Scale [85] Kessler 10 [35] Diet Habits Questionnaire [35] EuroQol's EQ-5D [35] Morbidity (hospital readmissions) and Mortality obtained by hospital records [35] Heart Healthy Eating [77] Heart Healthy Eating Self-Efficacy Scale (HHESES) [77]
	Condition-Specific Disease Severity	*Stroke/Cardiovascular:* Stroke-Adapted Sickness Impact Profile [85] Stroke Impact Scale [79] Stroke Self-Efficiacy Questionnaire [79] Cardiac Rehabilitation ssessment Tool [35] Chedoke-McMaster Stroke Assessment Activity Inventory [85]
	Physical Function	Grip Strength (Jamar handheld dynamometer) [79] Step test [79] Active Australia Survey [35] Walking activity measured by pedometer [35] 6-Minute Walk Test [35] Berg Balance Scale [85]
Other Outcomes	Patient Treatment Adherence	Self-report [35] Dropout rate, obtained from trial recruitment spreadsheet [35]
	Caregiver and Family Well-being	Caregiver Burden Inventory [59] Feetham Family Functioning Survey [59] Mastery of Stress Scale [59]
	Goal Attainment	Goal Attainment Scaling [85]
	Cost Effectiveness	EuroQol - 5D [79] Reported costs of staff time, equipment and facility costs (from hospital's financial database), cost estimates for other technology costs at current market value [35]

Design and Formative Evaluation

Studies that addressed design features with respect to acceptability and usability tended to use qualitative data collection strategies: focus groups, in-depth and semi-structured interviews [42,51,52,70,74,79,80], persona-based scenarios [50,51], as well opinion surveys using structured questionnaires [42,61,81-83]. Functionality (usability/feasibility) was tested within simulation environments [50,60]. A good understanding of the unique needs and characteristics of the end-users was

obtained through the use of interviews, observations, and focus groups [51]. End-users included clients, family caregivers, and HCPs (Table 2).

Implementation, Process, and Outcome Evaluation

Several methods and data collection strategies were used during pilot and small scale implementation studies to evaluate mHealth solutions used in the context of home and self-management for older adults. Studies investigating the adoption and implementation of mHealth solutions captured end-user utilization statistics through self-report [83] or automated data-generating features of the application itself [77,81]. Case studies including document review and key informant interviews were used to describe implementation across a health care system [72,73]. Opinions concerning barriers and facilitators to implementation were again captured through interviews and opinion surveys with key informants and end-users [46,74,80,81]. Costs of implementation were assessed using cost-benefit analysis techniques [35]. Core competencies in eHealth for HCPs were identified through a facilitated process with workshop participants [67].

Controlled trials assessing health outcomes associated with the use of mHealth solutions frequently incorporated standardized tools or scales designed for the specific health outcome or chronic condition of concern [59,79,84,85]. Parametric measures (eg, blood pressure, BMI, glucose levels) were used to determine changes or differences in health status [35,55,76]. One systematic review investigated the overall effectiveness (ie, cost, satisfaction, and quality of life) of eHealth using the Internet as a mechanism for interactive communication (instruction, information, monitoring) between patients and professional care providers [91]. Another review investigated the benefits of mobile phone interventions for long-term chronic condition management [71].

Frameworks for Planning Evaluation

McCullagh et al discussed phases of evaluation: (1) formative evaluation, conducted during application design and prototype testing of mHealth solutions in the self-management of chronic conditions; (2) summative evaluation, conducted during limited launches and pilot phases; and (3) population outcome evaluations, applied to full implementation after pilot phases, to determine the impact of complex interventions embedded in health care delivery systems [51]. The need for a common evaluation framework was identified, which incorporates all phases of mHealth solution development and supports an iterative process of development and knowledge transfer between developers, health care experts, and end-users. Similarly, Dale et al, in their work on mHealth solutions to support self-management by cardiac patients, followed a stepped process of evaluation starting with conceptualization, followed by formative research, and pre-testing to be followed by outcome evaluation through randomized controlled trials [77]. Each evaluation phase addresses different purposes in the development process.

In summary, methods used to evaluate mHealth solutions varied across the literature, including a variety of quantitative and qualitative data collection strategies and tools. Standardized tools were used for targeted outcomes of interest, and were often tailored to the chronic condition or client population under study. Other outcomes were more specific to reported behaviors and body metrics. In most cases, studies were either feasibility or pilot investigations, offering limited knowledge concerning the impact of full-scale implementation [51]. Researchers acknowledge the need for evaluation frameworks to guide a process of evaluation that follows the different phases of mHealth development and implementation from pilot studies to full-scale implementation [51,77].

Discussion

The purpose of this scoping review was to identify current practices and recommendations in designing, implementing, and evaluating mHealth technologies to support older adults and their caregivers in managing their chronic conditions while living at home. Lessons learned from this review are highlighted in Table 3 as they apply to the mHealth development process and from these, specific recommendations are offered. The lessons learned and recommendations will contribute richly to future mobile health developments for this rapidly growing population and technological context.

Table 3. Lessons learned in designing, implementing, and evaluating mHealth to support older adults with chronic conditions at home.

Design, Implementation, and Evaluation Domains	Recommendations
A good understanding of the end-users' context is critical	Engage end-users in activities such as personas and scenarios or simulations [50,53] with the technology; Involve app users and stakeholders early and often in the design process [46,88]; Consider universal design and accessibility principles to include engagement from end-users with a variety of abilities and needs [54]; Design apps that adapt to HCP's or patients' existing daily workflow and routines [58,68]
Less can be more on a mobile interface	Minimize navigation screens to two [53]; Include features with minimized complexity for end-users that are still based on the most advantageous and available technologies [51]; Match complexity and length of messaging to screen size for digestibility and readability [73]
Develop a strategy for interprofessional collaboration (ie, health care and technical expertise)	Create interdisciplinary development teams that consist of technology experts and health care professionals along with end-users and other affected stakeholders [46,51,52]; Ensure ongoing communication/sharing of ideas between health care and IT experts to enable successful implementation [72]
System and service reliability is essential for successful implementation	Be aware that malfunctions can cause frustration and negative perceptions of the solution [53]; Carefully design training approaches tailored to the needs of the end-users [50,71]
Look to business models for designing long-term maintenance and support	Carefully and realistically consider funds and timeline when planning for implementation [54]; Incorporate ongoing support and hardware maintenance/upgrades into budget [50]; Employ sound business models to secure investment from key government stakeholders [72]
Assemble a cohesive implementation team	Acknowledge that buy-in from both internal (end-users) and external (administrators/management) stakeholders is important [54]; Call on clinician champions as drivers to support the use of the solution [68]
An evaluation plan should be considered early on	Use an evaluation framework that incorporates all phases of mHealth application development [51]; Follow a stepped process of evaluation starting with conceptualization; consider a plan that will enable long term impact evaluation and costing [77]

Implications for Policy and Future Development

The findings from this review have implications for all stakeholders including researchers, clinicians, homecare providers, software developers, patients, and their families. In one of the few widespread technology implementation studies in community health care, it was clear that the extent of technology adoption was related to the end-users' perceived value or perceived risk of using the technology [73]. This supports one of the core constructs of normalization process theory pertaining to coherence or sense-making of the innovation [87]. It is therefore vital that clinicians, researchers, and mHealth designers consider hardware and software factors in the context of end-users' needs, preferences, and activities to ensure the solution is working for the user and not the other way around. Developers should strategically put together a team that has the capacity, including knowledge, skills, and resources to implement and maintain mHealth solutions, and who can speak to the specific needs of HCPs, patients, and their family supporters.

In only a few of the articles reviewed, were considerations and findings guided and presented within a theoretical framework [46,51,62,77]. The use of a framework enabled an approach that acknowledges the complexity of mHealth development when involving a diverse set of stakeholders and their interests in the midst of dramatic change in health care delivery. The magnitude of this challenge becomes more acute when we recognize the different levels of support required for older adults living at home—from total independence with the option to use mHealth technology as desired, to a gradation of dependency requiring the involvement of informal caregivers and health care providers. Further, the development of mHealth solutions presents its own unique challenges compared to traditional supports for older adults, when considering the kinds of expertise and systems adjustment required.

There are considerable implications for the patient when mHealth solutions are deployed within the context of health care. Researchers noted end-user concerns about implementing solutions in health care related to the idea of technology replacing, rather than supporting, human contact [73]. Accordingly, developers and health care providers must be sensitive to the needs and preferences of the patient and design solutions [54]. Patients, particularly older adults, have various levels of interest or literacy in technology; consequently, technology support needs to be factored into implementation plans [56]. In other words, mHealth is not a "one size fits all" approach.

Finally, there are policy implications at a population level. Mobile health has the potential to gather large amounts of health data that can be used to better inform interventions and care plans. However, there are many barriers to implementation and sustainability that limit the number of successful, evidence-based mHealth solutions that are implemented beyond the pilot or feasibility stage. For example, the additional costs of privacy / security testing, ongoing technology support/development, and software maintenance are a poor fit with government-supported funding cycles for research and development, where funds are typically delivered for a limited number of months or years [46].

Implications for Future Research

While this scoping review highlights a number of key design principles and lessons learned for the development and

implementation of mHealth solutions, there remain a number of gaps in the literature that should be addressed within future research priorities. First, there is little focus on sustainability of mHealth solutions, and few resources available for researchers to access when navigating the options and planning a sustainability plan. To address this, there may be opportunities for partnerships between industry and research to support the sustainability of an mHealth solution [46]. Second, there are few resources to support evaluating the long-term effect of using mHealth solutions. While the goals and objectives of each solution will vary, researchers would benefit from a theoretical framework to guide the cyclical, iterative process of design, implementation, and evaluation of mHealth technologies as whole entities rather than segmented parts. To this end, longer-term cohort studies and other research designs are needed that can attribute health outcomes to mHealth interventions within complex systems of health care. From a fiscal perspective, studies need to be designed that take into account the cost-effectiveness of new technologies [79].

Researchers also need to consider the unanticipated consequences and risks of mHealth solutions, as well as the potential inequities that may be created given unequal access and use of technologies in society. Potential risks to be considered include the following: (1) the potential for breaches in patient privacy and confidentiality [67,71], (2) the potential for mHealth solutions to replace rather than supplement clinical care [52], and (3) insufficient support or supervision for technologically assisted home-care rehabilitation [81]. It is critical that these risks and concerns, along with those yet unrecognized, are identified in order to manage them appropriately when any new intervention, and particularly technology-based interventions are implemented.

There is limited knowledge about the implementation science related to the adoption and acceptance of new technology in relation to home-based care for older adults. Researchers would benefit from a framework to evaluate the effectiveness of the process of implementing the mHealth solution. For example, where/when/how is support required by patients and their caregivers and how is this best addressed? More focused consideration needs to be given to patient empowerment using mHealth technology for self-management [88,89]. Further, researchers need to anticipate changing needs with different forms of technological experiences within an aging population. Investigators should consider how mHealth solutions targeted for older adults will need to evolve over time as age cohorts and technologies advance.

Limitations

Various limitations concerning this review need to be considered. First, true to scoping review methods, a quality assessment of selected papers was not used to exclude articles, although all were peer-reviewed. Results from studies using a variety of study designs as well as author opinions were incorporated into the findings of this review. Second, mHealth is a rapidly advancing field. Application of the reported findings may need to be reappraised within the context of a changing landscape of innovation. Third, this scoping review addresses a broad area of content and contexts, that is, different mHealth solutions, goals, and implementation contexts; multiple applications; different users, communities, and countries; and different chronic conditions with rare separation of single conditions from the context of multiple chronic conditions. This may limit transferability of the results to a specific context and present as prime areas for future systematic and realist reviews. Fourth, grey literature is not included; sources for this review were limited to articles published in peer-reviewed journals. Unpublished yet related information on the most current trends in this field may have been missed.

Conclusions

Developing effective mobile technologies with minimized risk to the quality of health care offered to older adults is a current research priority. Despite the potential benefits that mHealth solutions could offer, there is limited use of these technologies in the home. Interdisciplinary mHealth development teams need to consider specific factors when designing, implementing, and evaluating such technologies that will ultimately fit within the unique context of older adults at home and their care providers. Whether the target of mHealth solutions is the patient, family and/or HCPs, it is imperative to be working *with* these end-users rather than *for* them when designing, implementing, or evaluating mHealth solutions. Optimally, the cyclical and iterative process of mHealth development needs to be viewed as a whole with supportive frameworks to foster this.

The question and selection criteria for this review allowed for a broad range of mHealth technologies to be considered that apply to a variety of chronic conditions associated with aging. This paper presents some commonalities across these different contexts using thematic constructs to inform interconnected processes of design, implementation, and evaluation when developing mHealth solutions best suited to the needs of older adults living at home. At a time of rapid technological innovation, guidelines for research and development in mHealth need to be adaptable to continuous change as new tools become available [90], even as the health care delivery system itself experiences transitions toward community care. With the development of effective and efficient evidence-based technologies, mHealth solutions offer great potential for optimizing the health of an aging population.

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Authors' Contributions

NMM and LH conceived of the scoping review and participated in the design and coordination. JP participated in the design and coordination of the scoping review and drafting the manuscript. LH, S Ibrahim, S Isaacs, and NMM participated in title, abstract, and article review/selection and drafting the manuscript. MMR, RV, and AG contributed to manuscript development and refinement.

Conflicts of Interest

None declared.

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Abbreviations

COPD: chronic obstructive pulmonary disease
CVD: cardiovascular disease
HCP: health care provider
mHealth: mobile health
RCT: randomized controlled trial
SMS: short message service
WHO: World Health Organization

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Original Paper

Experiences With a Self-Reported Mobile Phone-Based System Among Patients With Colorectal Cancer: A Qualitative Study

Jenny Drott[1*], RN, MScN[‡]; Maria Vilhelmsson[2*], RN, MScN; Karin Kjellgren[2*], RN, PhD, Prof.; Carina Berterö[2*], RNT, PhD, Prof.

[1]Division of Nursing Science, Department of Medical and Health Sciences, Linköping University, Linköping, Sweden

[2]Division of Nursing Science, Department of Medical and Health Sciences, University of Linköping, Linköping, Sweden

[‡]Jenny Drott, Maria Vilhelmsson, Karin Kjellgren, Carina Berterö

[*]all authors contributed equally

Corresponding Author:
Jenny Drott, RN, MScN
Division of Nursing Science
Department of Medical and Health Sciences
Linköping University
IMH
Linköping, 581 83
Sweden
Phone: 46 013 286820
Fax: 46 013 286820
Email: Jenny.Drott@liu.se

Abstract

Background: In cancer care, mobile phone-based systems are becoming more widely used in the assessment, monitoring, and management of side effects.

Objective: To explore the experiences of patients with colorectal cancer on using a mobile phone-based system for reporting neurotoxic side effects.

Methods: Eleven patients were interviewed (ages 44-68 years). A semistructured interview guide was used to perform telephone interviews. The interviews were transcribed verbatim and analyzed with qualitative content analysis.

Results: The patients' experiences of using a mobile phone-based system were identified and constructed as: “being involved,” “pacing oneself,” and “managing the questions.” “Being involved” refers to their individual feelings. Patients were participating in their own care by being observant of the side effects they were experiencing. They were aware that the answers they gave were monitored in real time and taken into account by health care professionals when planning further treatment. “Pacing oneself” describes how the patients can have an impact on the time and place they choose to answer the questions. Answering the questionnaire was easy, and despite the substantial number of questions, it was quickly completed. “Managing the questions” pointed out that the patients needed to be observant because of the construction of the questions. They could not routinely answer all the questions. Patients understood that side effects can vary during the cycles of treatment and need to be assessed repeatedly during treatment.

Conclusions: This mobile phone-based system reinforced the patients’ feeling of involvement in their own care. The patients were comfortable with the technology and appreciated that the system was not time consuming.

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KEYWORDS

cancer; conventional content analysis; informatics technology systems; mHealth; self-reported mobile phone-based system; symptom monitoring

Introduction

The number of mobile subscriptions worldwide is estimated to be almost 7 billion. The growth rate until 2014 reached 2.6% globally, which is a low level indicating that the market is approaching saturation levels [1]. The continuous increase in mobile subscriptions is mostly due to growth in the developing world. The Global Observatory for eHealth of the World Health Organization defines mobile health (mHealth) as a "medical and public health practice supported by mobile devices such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices." The mobile phones of today have capacious memories, large screens, and operating systems that encourage the development of applications and other mobile phone-based systems [2]. There are great opportunities for mHealth in using these technologies.

The type of technology used in this study, mHealth, has been used by health care providers in home care for symptom management of patients with chronic diseases. Mobile phones are used for patients with chronic diseases such as hypertension, diabetes, heart disease, and asthma and also for a range of other health problems. Apart from enhancing the capacity to self-manage long-term conditions, mobile phone technology can have an impact on the understanding of a disease. It can also assist in lifestyle modifications and creates a supportive environment [3]. This may in turn have an effect on patients' independence, responsibility, and self-esteem. Mobile phone technology has advantages for users when it comes to portability, immediacy, convenience, comparatively low cost, efficiency, and simple usability [4]. Mobile phone-based health systems facilitate communication between patients and health care providers [3,4]. The increased number of mobile phone users creates new possibilities in cancer care.

Treatment of patients with advanced colorectal cancer (CRC) involves a postoperative combination of different chemotherapeutic agents. Oxaliplatin is one of the drugs used today, usually combined with 5-fluorouracil (5-FU) and folinic acid (leucovorin) [5,6]. Oxaliplatin is known to be highly neurotoxic, and neurotoxic side effects occur in most patients [7]. Severe neurotoxic side effects can affect the patient's daily life, limiting physical functions, and can be associated with depression and affected quality of life [8]. It is of great importance to identify patients who are at risk of developing high-grade neurotoxicity [6]. Early identification can eliminate the risk of developing chronic neurotoxic side effects with functional impairment [9]. Health care professionals have an important role in supporting patients and identifying and reporting early signs of neurotoxicity. It is necessary to have valid questionnaires to capture neurotoxic signs during and after oxaliplatin treatment [10,11].

The increased number of mobile phone users creates new possibilities for interventions with mobile phone-based technology. Such technology is useful for cancer care in prevention and early detection of cancer, treatment follow-up, and patient-health professional communication [12]. Mobile phone-based systems related to cancer care seem to have limited use and are employed only during limited phases of the care process. There is a need to improve the reliability and quality of content of what to be assessed by involving the medical profession in designing the systems [13,14]. In previous studies, patients used mobile phone-based systems to answer symptom questionnaires during treatment and to receive advice via the mobile phone [15,16]. Patients using mobile phone-based systems experienced improved management of their side effects. They felt secure knowing that their side effects were monitored by their health care provider and that they were participating in their own care [16,17]. In cancer care, mobile phone-based systems are becoming more widely used in the assessment, monitoring and management of side effects, self-care, and advice [17-19]. Few studies have used a mobile phone-based reporting system to monitor chemotherapy-induced side effects and to visualize distress with graphs and act on it. There are also few studies evaluating the usability of mobile phone-based systems in cancer care [18,19].

CQ: A Mobile Phone-Based System

In this study, a mobile phone-based system for self-reporting was used. This solution allows patients to answer structured questionnaires on their own mobile phones regarding their health and side effects of treatment. Patients' neurotoxic side effects in this study were identified in a self-reported, mobile phone-based system named Circadian Questions (CQ) (21st Century Mobile AB, http:// www.cqmobil.se). The CQ mobile phone-based system is designed to be platform independent. The CQ system is compatible with JAVA ME phones, iPhone, Android, iPad, and Windows Phone. The patients received platform-specific written information regarding installation of the system on their mobile phones.

The collected, identified data are transferred to a secure database via the Internet as data traffic, not SMS (Short Message Service) (Figure 1).

The answers are made available in real time and presented as graphs to the authorized health care professionals after they log in to a web interface. The cost for the patients is very low thanks to the use of data traffic; a set of answers (4K) costs 0.5 € cents as a maximum and the installation SMS at the start of the study costs roughly 10-20€ cents.

The research group modified and adjusted the Swedish version of the questionnaire OANQ to fit all mobile phone displays that are compatible with CQ [10]. In the adjustment process, some of the questions were condensed and some sentences shortened so that they would fit even the smallest displays of the JAVA ME mobile phones (many patients still use JAVA mobile phones), but this did not interfere with the content of the questionnaire. Example: *difficulty identifying objects in your hand (eg, coin)* was condensed to; *difficulty identifying (eg, a coin in your hand)* (Figure 2). All the questions had a similar structure, and the patients answered them in a numerical rating scale in the mobile phone by pressing a number between 1 and 5. The condensed questions were tested on some of the patients' representatives in advance to check that the content and understanding of the questions were preserved.

When the health care professionals initiated the transfer of the questionnaire to the individual mobile phone, they used a

calendar function to fill in the specific dates that the patient had received the questions. The dates in the calendar were set according to each patient's specific chemotherapy regime. The calendar was adapted to each specific patient, and the chosen questionnaire was sent out to the patient at exactly the right moment in the treatment cycle to attain individual customized assessments. This calendar function was specifically developed for this project or study to enhance individual customized measurements.

The aim of this study was to explore the experiences of patients with CRC of using a mobile phone-based system for reporting neurotoxic side effects.

Figure 1. The collected and identified data are transferred safely to a secure database via the Internet as data traffic (reproduced with permission from 21st Century Mobile AB).

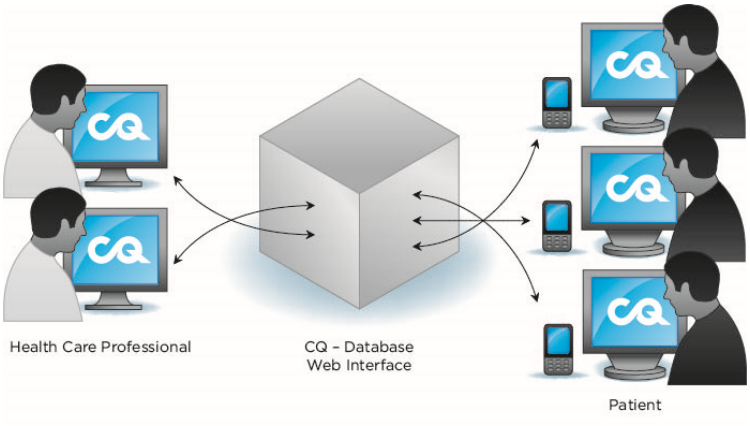

Figure 2. Example of a condensed question in the mobile phone display (reproduced with permission from 21st Century Mobile AB).

Methods

Study Population

This study is a part of a larger study with descriptive data of the frequencies of existing neurotoxicity and impact on daily life in patients with CRC cancer. Eleven patients were included in the present study from March to August 2014. One patient declined participation because of serious illness and a long hospital stay. Patients were included from 4 hospitals in the south of Sweden—2 university hospitals and 2 regional hospitals. Patient's inclusion criteria were as follows: at least 18 years of age; had been treated with 5-fluorouracil (5-FU) and folinic acid (leucovorin) in combination with oxaliplatin postoperatively in an adjuvant setting for stage II-III CRC; ability to speak and understand the Swedish language; and had answered CQ questionnaires on their own mobile phone to assess neurotoxicity. Every patient answered questionnaires using the mobile phone-based system CQ. At the time of the telephone interview, the patients had diverse experiences of answering the questionnaires using their mobile phones. The time they had used CQ varied from 1 to 10 months.

Data Collection

Data were collected through qualitative interviews. One of the authors (MV) contacted the patients and interviewed them by telephone. A semistructured interview guide was used. The questions asked were (1) what did you think of answering the questionnaire with repeated questions via a mobile phone? (2) what did you think of registering your side effects via a mobile phone? (3) were there any advantages in answering questions via a mobile phone? (4) where there any disadvantages in answering questions via a mobile phone? (5) could something in the mobile phone reporting system be improved? To clarify some parts of the interview, questions such as, "can you tell me more about that?" or "can you clarify that?" were asked. The interviews were audio digitally recorded and lasted between 12-31 minutes (mean 20). The interviews were transcribed verbatim.

Analysis

With the explorative aim of the study in mind, the respondents' transcribed interviews were analyzed as a whole using techniques of conventional qualitative content analysis [20,21]. Qualitative content analysis can be applied to transcribed interviews because there is a text to work with. The analyses were performed by three of the authors (JD, MV, and CB). Before beginning the analyses, the authors read the transcribed interviews. Statements with similarities were grouped together and summarized into tentative clusters based on the questions asked. These tentative clusters were reviewed in detail, and all the included statements were scrutinized. Unclear statements were explored with respect to the original context. Through iterative in-depth discussions among all the authors, the statements were reclustered step by step, and a more logical and complete structure gradually emerged. These completed structures of original text were again reviewed in their original context and condensed into final clusters by the three authors, and final adjustments were made. Thus, all the clusters were validated through systematic repeated reviews of the data. To confirm and illustrate the clusters identified, quotations related to the clusters were selected during the analysis process. The quotes used in the Results section illustrate examples of patients' statements. The interviews and transcriptions were all in Swedish. To produce this paper, great care was taken to translate the quotations with the support of a native, English-speaking translator.

Ethics

All data were treated carefully and confidentially. All patients provided oral and written informed consent in line with the Declaration of Helsinki [22]. Ethical approval was obtained from the Regional Ethical Review Board (record no.: 2012/301-31).

Results

Eleven patients were included in the analysis, 4 men and 7 women. They were aged between 44-68 years, median 65.

Three main clusters were identified and constructed during the analysis, and given the names "being involved," "pacing oneself," and "managing the questions." These are shown in Table 1. Each of the main clusters includes a number of subclusters at varying levels of abstraction, and the clusters are linked together by the underlying meanings.

Table 1. Overview of clusters and subclusters.

Being involved	Pacing oneself	Managing the questions
Being a participant	Having impact	Need to be alert
Being aware	Having support	Recognition
Getting knowledge		Discovering "the gray area"
Being a contributor		

Being Involved

The patients experienced that they were *participating* in their own care in various ways when they used the self-reporting mobile phone-based system. Patients were aware that the answers they gave were monitored in real time and taken into account by health care professionals when planning further treatment.

> *...they were very careful, at least when I had the treatment, to check up on these questions. They've changed my medication several times and now I'm doing really well. So that's very positive.* [Patient no.: 8]

> *...it's very good if someone can do a follow-up immediately after you've sent the answers and that you get, as in my case, a question or someone giving you a call who says that you've answered this and that and we'd like to talk to you about it and so on. That was great. I think that's very useful, definitely.* [Patient no.: 3]

This reporting system was perceived to be flexible and patients were comfortable with it. The results of the study point out the usability of the system. The initial reaction to the questionnaires was that they contained a large number of questions, but patients found them relevant to the treatment and therefore meaningful. If the patients had a problem such as a hearing disability, it was more convenient to answer questions via the questionnaire on the mobile phone than having a conversation on the telephone. Patients stated that answering a questionnaire on the mobile phone was easier and less time consuming than answering a paper questionnaire and having to post it. Patients reflected on the different ways of communicating and personal contact with medical staff.

> *I think it can be a really good instrument // I don't think that you can ignore the importance of a physical*

> *meeting completely. You might think it's enough to answer the questionnaire, you have an alternative.* [Patient no.: 2]

Answering the questionnaires also made the patients more *aware* of the side effects, both in a positive way and in a negative way. This awareness provided the patients and the health care professionals with *knowledge* about the side effects of treatment. Patients were faced with aspects of the diagnosis that could be a strain emotionally, and sometimes upsetting. This is something that can be found in all forms of questionnaire, as they can make patients aware of consequences and effects they have not thought about before.

The patients had a sense of *contributing* to something more beside their own care. By answering the questionnaires via their mobile phones, they contributed to extending and developing oncology care and/or nursing.

> *…with my participation I am a part of development of oncological treatment. It is about understanding how patients are doing during treatment and also about decreasing side effects for people that need to have this chemotherapy in the future.* [Patient no.: 6]

Pacing Oneself

The main reason for the patients' appreciation of this self-reporting system was the possibility to *pace oneself*. As a patient, you have options regarding when and where you want to answer the questionnaire; you can choose a time and a place to answer the questions and you can do it in peace and quiet. For patients, this was an important advantage of using a mobile phone-based system. A questionnaire on paper would probably have resulted in patients' withdrawal from the study. A reminder to answer the questionnaire was sent out to the patient's mobile phone at 4 pm if the questionnaire had not been answered before that time.

> *The reminder is good, since it's not always suitable to answer the questionnaires at the first "mailing." // Questionnaires on the mobile phone could be answered almost anywhere and whenever you wanted to.* [Patient no.: 3]

> *I can answer when I want. For example, the last time I answered the questions I was sitting in my car on the way home from Stockholm. Well, the accessibility… and I can decide for myself. // More than if we were to have telephone contact. This is freedom, I can do it wherever I want to.* [Patient no.: 7]

Answering the questions via this self-reporting system was perceived as easy and not time consuming. The process of answering was quickly completed considering the total number of questions. The questions in the original questionnaires were quite long, so when using them in the mobile phone-based system, the questions were shortened. The patients stated that the questions were condensed, but were clear and easy to answer.

> *It's only a few "clicks" and it's very easy. Especially when you just answer with a number and don't have to write things down.* [Patient no.: 4]

> *I always have my mobile phone with me, so it's easier. It's quick and better than surveys on paper and computers.* [Patient no.: 5]

The system was not difficult for the patients when it comes to usability. However, some patients encountered technical problems or needed help with the functioning of the questionnaire. They all had opinions about the *support*; support was just a phone call away and easily accessible. On some occasions, there were glitches in the system due to problems with the mobile network accessibility in the countryside.

Managing the Questions

The patients *needed to be alert*, at least at the beginning of the study, when answering the questions. Patients pointed out that they could not routinely answer the questions in the beginning. They needed to be observant due to the construction of the questions.

> *You need to observe how the questions are formulated. The construction of the questions sometimes differs, which affects how you value the answer on the scale. The questionnaire demands that you are alert and really read what is stated in each question.* [Patient no.: 1]

> *I think there are a lot of questions but the questions are similar, so I learned to manage them.* [Patient no.: 9]

After a while, there was *recognition*; there were a great number of questions, but the patients found that acceptable because they became familiar with the structure. Even though there were many questions, the patients stated that they managed to answer them smoothly and quickly.

At the beginning, some of the patients had trouble understanding why the questions were repeated continuously at certain intervals. Gradually there was an understanding of the need for this repetition because the side effects could vary during treatment. Patients recognized the fact that the same side effects needed to be measured before and after every dose of chemotherapy to identify and follow-up the side effects of treatment.

> *The treatment I receive affects my entire body, so I don't think that it's possible to reduce the number of questions. These are the side effects I usually have, so, well I don't think that it';s possible to reduce the number of questions.* [Patient no.: 4]

Some patients pointed out that they had side effects that could not be conveyed in the questionnaire, and therefore asked for space to write comments. The patients highlighted so called "gray areas" when trying to answer the questions; there were side effects that could not be defined by a number on the scale and there were problems that patients wished to explain using words instead. When patients thought they were in this "gray area," they would have preferred to talk to a physical person and explain their issues.

> *… but it's a bit difficult, you can't give details, you have to give a number. For example, if you have problems with eyesight. You know, I press on one eye, left eye, and the eyesight disappears completely. Then it comes back gradually when I release the pressure. So that's a side effect I can't get across with the questions.* [Patient no.: 11]
>
> *There are questions that I cannot identify with, and sometimes it can be hard to select the proper rating for my side effects.* [Patient no.: 10]

Patients could have distressing and painful side effects such as pricking sensations but they were able to cope with them. Some patients received phone calls from health care personnel who were observing the answers. Patients were grateful for the telephone contact and considered this as a bonus in the study.

Discussion

The findings of this study highlight the experiences of patients with CRC of using a mobile phone-based system for reporting neurotoxic side effects. Patients felt involved in their own care. Symptom monitoring by means of a mobile phone gave the patient the opportunity to communicate the neurotoxic side effects of the treatment to medical staff, who could act on it within a short period. Real-time symptom monitoring gives an accurate image of the patient's experience of the side effects. Adaption of individual doses of chemotherapy is possible using mobile phone technology according to Weaver et al [16]. Real-time monitoring of toxicity enables optimization of dose increase and effective management of side effects [16]. As reported in another study, delayed self-reporting of chemotherapy side effects can lead to weaker insights into the symptom burden, partly due to patients forgetting the severity of the side effects [23].

There was an increased awareness of neurotoxic side effects among patients. Identification of neurotoxic side effects in patients with CRC can eliminate the risk of functional impairment regarding chronic neurotoxicity [9]. The mobile phone-based system used in this study is constructed for individual flexibility and enables the questions to follow every patient's specific cancer treatment regime.

According to De Jongh et al [24], mobile phone-based systems may facilitate self-management of long-term illnesses. Patients express interest in using these kinds of mobile phone-based system. However, the evidence for this is based on a small number of trials, and further research is needed to gain more information about the long-term effects, acceptability, costs, and risks of such interventions. The mechanisms behind short- and long-term acceptability, such as message content and frequency, need further research [24].

The issues of time spent on answering the questionnaire and accessibility of mobile phone-based system were essential for patients. The patients appreciated that the system was not time consuming. The questions in the questionnaires were condensed to fit the displays of all mobile phones compatible with the CQ system [11]. Patients found them easy to understand and meaningful to answer. The CQ system is not designed for a particular mobile phone platform. It can thus be used on a wide range of different platforms, which makes it accessible to a large proportion of the population.

It is necessary, though, that the side effects are followed by the medical staff and the health care professionals by means of graphs. In a study by McCann et al [17], they used an automated system where health care professionals observed patients' side effects of chemotherapy-related toxicity in real time. Patients reported symptoms on days 1-14 after their first 4 cycles of chemotherapy. Data were registered in a system, and advice was sent to the patient [17].

Today, short hospital stays are common, and many patients are required to recover at home. For some patients, this can be convenient and improve overall quality of life. But again, other patients may need prolonged support and medical assistance to be able to recover after their hospital stay. Monitoring these patients and conducting follow-up visits are very time consuming for health care professionals. This is problematic given the increasing workload for health care staff today. A system that facilitates the contact between the patients and the oncology team with early detection of side effects in chemotherapy treatment could not only improve patients' health but also be cost-efficient. In a study about hypertension management, health care professionals stressed the importance of being accessible to patients and that an interactive self-report system increased the contact with patients. In that study, patients' self-management of their hypertension was examined [25,26]. Feedback provided by health care staff is appreciated by patients as a "bonus" and a confirmation of the fact that they could have an impact on their own care. The prevention of future complications and improved cancer treatment are of great importance to the patients. Mobile phones have previously been successfully used in different areas of health care. Even so, there are surprisingly few research studies that focus on mobile phone technology for disease and health monitoring [27,28].

In the larger study by Drott et al [29], neurotoxic side effects were monitored for a considerably longer period of time than in previous studies. Previous studies have followed patients for a few cycles of treatment [15,16]. Our study is unique in that the patients' neurotoxic side effects were registered in CQ from the start of chemotherapy and up to 1 year after treatment. Every patient answered the CQ questions 4 times during every treatment cycle. In this study, the 11 individuals were at different stages in their chemotherapy treatment and therefore they had answered questionnaires in the CQ system for varying lengths of time. The interval at which questionnaires were sent out could be adjusted individually to each specific patient thanks to the calendar function. Real-time symptom monitoring and longitudinal follow-up of side effects give a proper impression of the patient's experience and symptom burden.

In cancer care, mobile phones are becoming more widely used in the assessment, monitoring and management of side effects, self-care, and advice [17-19]. Our results are unique because our mobile phone-based system is individually tailored for each patient. We also focus on neurotoxicity, and there are no other studies that measure neurotoxicity in real time, so frequently and for such a long time. Some patients pointed out that they

had side effects that could not be conveyed in the questionnaire, and therefore asked for space to write comments. The patients highlighted so-called " *gray areas"* when trying to answer the questions; there were side effects that could not be defined by a number on the scale and there were problems that patients wished to explain using words instead. When the patients perceived themselves as in this " *gray area*," they would have preferred talking to a physical person, to explain their issues. These results pointed out that mobile phone-based system is a complement to the physical meeting with medical staff.

Limitations of the Study

This study has some limitations. The sample size of 11 participants may seem small, but this sample size is relevant in qualitative research [30]. This is a starting point for further research and with respect to the diagnosis of cancer, researchers have to take into account vulnerable groups of patients, makes it difficult to find patients eligible for studies. The telephone interviews in this study were in addition to the regular care routine. Telephone interviews are generally shorter than face-to-face interviews, and nonverbal information is lost. An advantage of telephone interviews may be that they save time because no one involved in the interview needs to travel to a physical meeting. As in all interviews and surveys, there could be a risk of including only those people with a positive attitude.

Conclusions

The results of this study show that this mobile phone-based system reinforced the patients' feeling of involvement in their own care. The patients felt comfortable with this mobile phone-based technology, it was accessible and usable.

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Conflicts of Interest

None declared.

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Abbreviations

CQ: Circadian Questions
CRC: Colorectal Cancer
mHealth: mobile health

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Original Paper

Evaluation of the Use of Home Blood Pressure Measurement Using Mobile Phone-Assisted Technology: The iVitality Proof-of-Principle Study

Liselotte W Wijsman[1], MD; Edo Richard[2,3], PhD, MD; Ricardo Cachucho[4], Master Degree; Anton JM de Craen[1†], PhD; Susan Jongstra[3], MD; Simon P Mooijaart[1,5], MD, PhD

[1]Leiden University Medical Center, Department of Gerontology & Geriatrics, Leiden, Netherlands
[2]Radboud University Medical Center, Department of Neurology, Nijmegen, Netherlands
[3]Academic Medical Center Amsterdam, Department of Neurology, Amsterdam, Netherlands
[4]Leiden Institute of Advanced Computer Sciences, University of Leiden, Leiden, Netherlands
[5]Institute of Evidence-Based Medicine in Old Age, Leiden, Netherlands
[†]deceased

Corresponding Author:
Simon P Mooijaart, MD, PhD
Leiden University Medical Center
Department of Gerontology & Geriatrics
Albinusdreef 2
Leiden, 2300 RC
Netherlands
Phone: 31 (0)71 5266640
Fax: 31 (0)71 5266881
Email: S.P.Mooijaart@lumc.nl

Abstract

Background: Mobile phone-assisted technologies provide the opportunity to optimize the feasibility of long-term blood pressure (BP) monitoring at home, with the potential of large-scale data collection.

Objective: In this proof-of-principle study, we evaluated the feasibility of home BP monitoring using mobile phone-assisted technology, by investigating (1) the association between study center and home BP measurements; (2) adherence to reminders on the mobile phone to perform home BP measurements; and (3) referrals, treatment consequences and BP reduction after a raised home BP was diagnosed.

Methods: We used iVitality, a research platform that comprises a Website, a mobile phone-based app, and health sensors, to measure BP and several other health characteristics during a 6-month period. BP was measured twice at baseline at the study center. Home BP was measured on 4 days during the first week, and thereafter, at semimonthly or monthly intervals, for which participants received reminders on their mobile phone. In the monthly protocol, measurements were performed during 2 consecutive days. In the semimonthly protocol, BP was measured at 1 day.

Results: We included 151 participants (mean age [standard deviation] 57.3 [5.3] years). BP measured at the study center was systematically higher when compared with home BP measurements (mean difference systolic BP [standard error] 8.72 [1.08] and diastolic BP 5.81 [0.68] mm Hg, respectively). Correlation of study center and home measurements of BP was high (R=0.72 for systolic BP and 0.72 for diastolic BP, both P<.001). Adherence was better in participants measuring semimonthly (71.4%) compared with participants performing monthly measurements (64.3%, P=.008). During the study, 41 (27.2%) participants were referred to their general practitioner because of a high BP. Referred participants had a decrease in their BP during follow-up (mean difference final and initial [standard error] −5.29 [1.92] for systolic BP and −2.93 [1.08] for diastolic BP, both P<.05).

Conclusion: Mobile phone-assisted technology is a reliable and promising method with good adherence to measure BP at home during a 6-month period. This provides a possibility for implementation in large-scale studies and can potentially contribute to BP reduction.

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KEYWORDS

mobile phone; home-based measurements; hypertension; dementia

Introduction

High blood pressure contributes to the global burden of disease, accounting for 9.4 million deaths per year [1]. With a prevalence as high as 78% among the 65-plus population in Europe, it is one of the most common chronic conditions in primary care [2]. Although the prevalence is predicted to further increase over the coming years, only 70% of all hypertensive patients are aware of having hypertension [3,4]. In spite of widely available effective ways to reduce blood pressure, rates of hypertension control are still far from optimal [2,5-7]. In one study including 5296 participants, blood pressure control was achieved in only 30% of patients, who were aged 60 years or older [8].

The increasing availability of the Internet, mobile phones, and health sensors provides the potential to interactively administer health interventions at home. Recent surveys show that at least 75% of the European population uses the Internet on a regular basis, with almost half of them using a mobile phone to access the Internet (smartphone) [9]. Adults aged 65 years and older are the fastest-growing group of Internet users [10]. Older adults have a high interest in self-assessment health tools [11]. This enables people to measure blood pressure at home, with the potential of direct feedback and treatment adjustments. Furthermore, previous studies show that home blood pressure measurements, when compared with clinic blood pressure measurements, are in fact a stronger prognostic indicator of cardiovascular events [12-14]. It could therefore be effective to identify patients at risk of cardiovascular events and thereby prevent the occurrence of cardiovascular complications [12,15]. In addition, it provides a potential for large-scale implementation and data collection. However, data on feasibility of long-term home blood pressure measurements, using the Internet and mobile phones, are scarce [16-18].

The aim of this proof-of-principle study was to evaluate home blood pressure measurements using mobile phone-assisted technology. For this, we investigated (1) the association between study center and home blood pressure; (2) the adherence to perform home blood pressure measurements according to a monthly or semimonthly measurement protocol; and (3) referrals, treatment consequences and blood pressure reduction after a raised home blood pressure was diagnosed.

Methods

Study Design

iVitality is a Web-based research platform that consists of a Website, a mobile phone-based app, and sensors that are connected with or already integrated in the mobile phone to measure blood pressure [19]. This iVitality study is a proof-of-principle study in which participants were randomized to perform home blood pressure measurements according to a monthly or semimonthly measurement protocol, during a period of 6 months. The different measurement protocols are described in more detail in the "Follow-Up Measurements" paragraph below.

Study Participants

We chose to perform this study in people with a parental history of dementia because (1) they have a higher risk of both hypertension and dementia, making them a potentially suitable target group for large-scale preventive studies and (2) they are highly motivated to participate in preventive studies [13,14,15]. Other inclusion criteria were (1) age 50 years and older; (2) familiar with and in possession of a mobile phone with iOS or Android (version, 2.3.3 or higher) software; and (3) motivated to measure health characteristics at home several times a month, during a 6-month period. Exclusion criteria were a medical diagnosis of dementia and/or any other cognitive disorder and a medical history of stroke and/or transient ischemic attack.

Participants were recruited through advertisements in memory outpatient clinics, nursing homes, general practices, and on the Website, and in the newsletter of the Dutch Alzheimer Foundation (Alzheimer-Nederland). If all of the inclusion criteria were met, participants received detailed study information in print. They visited the study center at Leiden University Medical Center or Academic Medical Center Amsterdam at baseline, where they received information about the study and baseline measurements were performed by a study physician or research nurse. Written informed consent was obtained from all participants. The medical ethical committee of Leiden University Medical Center, the Netherlands, approved the study.

Baseline Measurements

Enrolment and follow-up took place from September 2013 to January 2015. In preparation for the first visit to the study center, all participants completed a Web-based questionnaire on education, medical history, and medication use. During the visit to the study center, detailed information about the iVitality app and instructions on how to use it were given. History of hypertension and medication use was self-reported. Blood pressure was measured twice at baseline on the upper left arm, in sitting position with a fully automatic electronic blood pressure monitor. Participants were instructed in the use of the home blood pressure monitor.

Follow-Up Measurements

During a 6-month period, participants received automatic messages on preprogrammed days at self-chosen time points on their mobile phone, which reminded them to measure blood pressure. Participants with an Android mobile phone used an A&D blood pressure monitor (A&D Company, Ltd; model UA 767 Bluetooth) which was connected to the mobile phone and automatically transferred the results to the iVitality app by Bluetooth [20]. Participants with an iPhone used an OMRON (OMRON Healthcare Company, Ltd, model M6W and M6AC [HEM-7322-E]); they manually typed their blood pressure values and heart rate in the iVitality app [21]. During the first week and the last week of the study, all participants performed

blood pressure measurements according to the guideline of the European Society of Hypertension [13]. In short, participants were asked to measure their blood pressure twice at both morning and evening, at least for 4 days during the first week of the study, with day 1 being discarded [13]. For the rest of the study period, blood pressure was measured according to 2 different study protocols, to which participants were randomly assigned by a computerized program at baseline. Randomization was performed in a 1:1 manner stratified for sex. In the monthly protocol, participants performed measurements in the morning and evening of 2 consecutive days. In the semimonthly protocol, blood pressure was measured in the morning and evening of only one day. Blood pressure was measured twice at each measurement; the mean of both measurements was used. Reminders to perform blood pressure measurements were sent the evening before the measurement day and at the actual day on which the participant was expected to perform the blood pressure measurements. When participants did not perform their blood pressure measurements, they received a reminder the day after. This reminder was sent automatically by the Website of the iVitality research platform, and therefore, was a standardized procedure. The measured blood pressure was sent as a message to the mobile phone. Blood pressure measurements were also graphically visible in the app. Participants with a mean systolic home blood pressure above 135 mm Hg and/or 85 mm Hg for diastolic home blood pressure during these days were considered as possibly having hypertension and therefore referred to their general practitioner (GP) [13].

Statistical Analysis

Characteristics of the study participants are reported as mean with standard deviation for continuous variables and as number with percentage for categorical variables. We used Pearson's correlation coefficient to calculate the correlation between home and study center blood pressure measurements. To investigate agreement between study center and home blood pressure measurements, we computed the mean and the difference in study center and home blood pressure measurements and visualized this in a Bland–Altman plot.

Adherence was defined as the actual performance of all blood pressure measurements within 1 week of the time point they were expected to perform their measurements and for which the participant received reminders through the mobile phone app. For each participant, we calculated the percentage of adherence during follow-up. Difference in adherence between the monthly and semimonthly measurement protocol was assessed using a Mann–Whitney *U* test. In this proof-of-principle study, only participants who completed the 6-month period were used in the primary analysis. In a sensitivity analysis, we included all participants who were included at baseline.

We investigated the difference in blood pressure during the first week and the final week after 6 months using a paired *t* -test. For both blood pressure during the first week and final blood pressure, we calculated the mean values of all blood pressure measurements performed during the first and last week, with day 1 of both weeks being discarded [13].

All analyses were performed using SPSS (version 22.0.0, SPSS Inc., Chicago, IL, USA).

Results

Baseline characteristics

Figure 1 shows the inclusion flowchart of participants. A total of 195 participants registered on the Web to participate. Of those, 27 did not meet inclusion criteria and 17 registered after recruitment had been completed because of a time lag between registration on the Web and baseline visits. Our study population therefore included 151 participants. A number of 66 (43.7%) participants were assigned to perform blood pressure measurements at a monthly interval; 85 (56.3%) participants were assigned to perform semimonthly blood pressure measurements (Figure 1).

Baseline characteristics are shown in Table 1. Mean age was 57.3 (standard deviation [SD] 5.3) years; 107 (70.9%) participants were female. Of all participants, 56 (37.1%) used iPhone and 59 (39.1%) used Samsung. Mean systolic and diastolic blood pressure measured at the study center was 137.8 (SD 18.2) and 85.4 (SD 10.8) mm Hg, respectively. Participants within the monthly protocol had a higher body mass index, systolic blood pressure, and diastolic blood pressure at baseline (Multimedia Appendix 1). A number of 32 (21.2%) participants had a history of hypertension and used antihypertensive medication, most commonly diuretics (15 participants [46.9% of hypertensive participants]). This did not differ between the monthly and semimonthly protocol.

Table 1. Baseline characteristics of iVitality participants.[a,b]

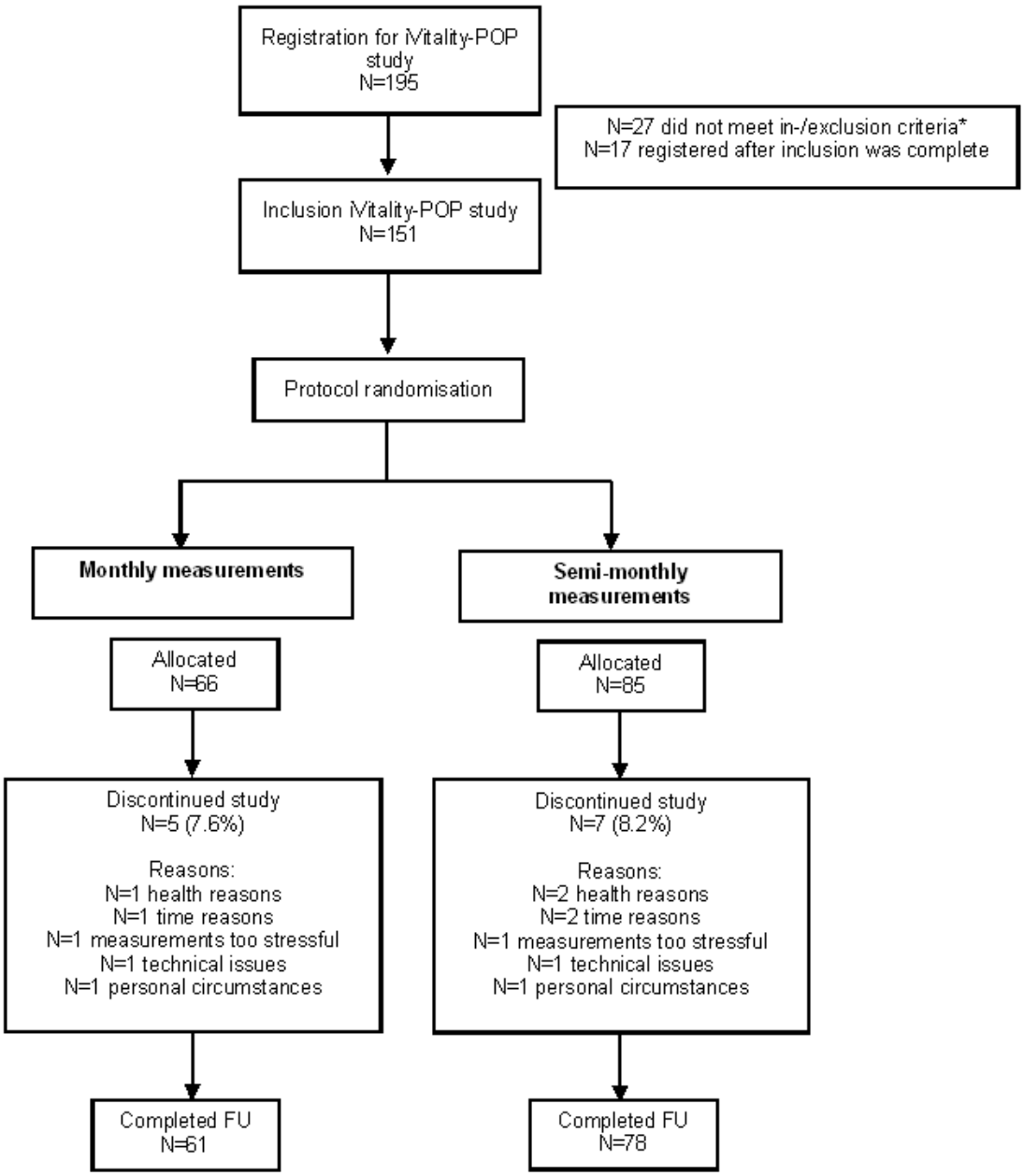
Demographics		All participants (N=151)
Age (years)		57.3 (5.3)
Female, n (%)		107 (70.9)
Body mass index		26.4 (4.0)
Highest education level, n (%)[c]		
	Low	16 (10.6)
	Middle	44 (29.1)
	High	88 (58.3)
Study center, n (%)		
	Academic Medical Center Amsterdam	55 (36.4)
	Leiden University Medical Center	96 (63.6)
Type of phone, n (%)		
	iPhone	56 (37.1)
	Samsung	59 (39.1)
	HTC	15 (9.9)
	Other	21 (13.9)
Blood pressure		
	Systolic blood pressure (mm Hg)	137.8 (18.2)
	Diastolic blood pressure (mm Hg)	85.4 (10.8)
	Heart rate (bpm)	67.2 (10.2)
Vascular risk factors, n (%)		
	History of hypertension	32 (21.2)
	History of diabetes mellitus	2 (1.3)
	History of MI	4 (4.6)
	History of arrhythmia	11 (7.3)
	History of heart failure	3 (2.0)
	Hypercholesterolemia	14 (9.3)
	Current smoker	14 (9.3)
Antihypertensive medication, n (%)		
	Diuretics	15 (9.9)
	ACE inhibitors	6 (4.0)
	Beta-blockers	11 (7.3)
	Calcium antagonists	6 (4.0)
	Other	9 (6.0)
No of antihypertensive medication, n (%)		
	1	21 (65.6)
	2 or more	11 (34.4)

[a]Data represent mean (standard deviation) unless stated otherwise

[b]Abbreviations: MI, myocardial infarction; MMSE, mini-mental state examination.

[c]Missing data for n=3 participants. Low: primary education, lower education, MAVO/MULO. Intermediate: high general secondary education (HAVO, HBS), Preparatory Scientific Education (VWO), intermediate professional education (MBO). High: higher professional education (HBO), academic education (university).

Figure 1. Flowchart of study participants. *Reasons why participants did not meet in-/exclusion criteria were as follows: n=4 did not have the correct software version of the mobile phone; n=6 did not have parents with dementia; n=6 were on holidays during the inclusion period; n=7 were not interested to participate after reading the study information; n=4 because of other reasons.



Main findings

The association between study center and home blood pressure during the first week is shown in Figure 2. The correlation between study center and home measurements was high for both systolic (R=0.72, P<.001) and diastolic blood pressure (R=0.72, P<.001; panel A). Systolic blood pressure at the study center was systematically 8.72 mm Hg higher (standard error [SE] 1.08) and diastolic blood pressure was 5.81 (0.68) mm Hg higher when compared with home blood pressure measurements (panel B). The Bland–Altman plot shows that the difference between the measurements was randomly distributed over the mean of the measurements, indicating that there was no systematic bias in agreement between the study center and home measurements. The 95% limits of agreement for the comparison were −16.82 to 32.82 mm Hg for systolic blood pressure and −9.71 to 21.33 mm Hg for diastolic blood pressure.

Adherence to the monthly and semimonthly blood pressure measurement protocols is shown in Figure 3. In total, 12 participants did not complete follow-up: 5 (7.6%) participants in the monthly measurement protocol and 7 (8.2%) participants in the semimonthly measurement protocol. Median adherence to perform blood pressure measurements was 71.4% (Figure 3). Participants performing semimonthly blood pressure

measurements were more adherent (median adherence 71.4%) when compared with participants performing monthly blood pressure measurements (64.3%, *P*=.008). There was no difference in adherence between participants who entered their blood pressure measurements manually and participants who used a Bluetooth connection to transfer the measurements (data not shown). Furthermore, a sensitivity analysis in which we investigated the adherence of all 151 participants who were included at baseline, showed similar results: adherence was higher in participants who performed semimonthly blood pressure measurements (median adherence 85.7%) when compared with participants performing monthly measurements (71.4%, *P*=.002; Multimedia Appendix 2). Discontinuation was highest within the first weeks of follow-up for both measurement protocols.

Table 2 presents the difference in final and initial home blood pressure measurements. Among all participants, there was no difference between final and initial blood pressure, for both systolic (mean difference [SE] −1.30 [1.10] mm Hg, *P*=.240) and diastolic (−0.90 [0.51] mm Hg, *P*=.081) blood pressure. There were 41 out of 151 (27.2%) participants who were referred to their GP because of a high blood pressure, of whom 35 (85.2%) actually visited their GP. In referred participants, blood pressure decreased significantly during the study, both systolic (mean difference [SE] −5.29 [1.92] mm Hg, *P*=.011) and diastolic (−2.93 [1.08] mm Hg, *P*=.012). Furthermore, no difference was found between final and initial blood pressure for both systolic and diastolic blood pressure between the monthly and semimonthly protocol (data not shown). In 7 out of 41 (17.1%) participants, blood pressure lowering medication had been started or changed.

Table 2. Difference between the first and last home blood pressure measurement.[a,b]

		Systolic blood pressure				Diastolic blood pressure			
		First	Last	Diff. (SE)	*P*-value	First	Last	Diff. (SE)	*P*-value
All participants[c]		128.22 (1.45)	126.92 (1.31)	−1.30 (1.10)	.240	79.30 (0.90)	78.40 (0.73)	−0.90 (0.51)	.081
By protocol									
	Monthly measurements, n=45	128.23 (2.25)	128.15 (2.25)	−0.08 (1.98)	.968	80.08 (1.38)	78.87 (1.18)	−1.21 (0.84)	.156
	Biweekly measurements, n=58	128.20 (1.91)	125.96 (1.54)	−2.25 (1.20)	.068	78.70 (1.20)	78.02 (0.92)	−0.67 (0.64)	.304
By referral									
	Not referred, n=78	122.61 (1.27)	122.59 (1.28)	−0.02 (1.29)	.987	76.71 (0.91)	76.45 (0.80)	−0.25 (0.56)	.654
	Referred, n=25	145.72 (1.96)	140.43 (1.91)	−5.29 (1.92)	.011	87.22 (1.66)	84.44 (1.02)	−2.93 (1.08)	.012
	Referred and visited GP, n=23	146.02 (2.03)	140.98 (2.00)	−5.04 (2.07)	.023	87.22 (1.66)	84.44 (1.02)	−2.79 (1.17)	.027
	Referred and changed/started BP med., n=5	153.73 (3.93)	141.62 (4.83)	−12.12 (6.65)	.142	90.62 (2.64)	83.79 (1.55)	−6.83 (2.29)	.080

[a]Data represent the mean difference (standard error) in mm Hg of final and initial blood pressure.

[b]Diff, difference; SE, standard error; GP, general practitioner; BP, blood pressure.

[c]Missing data for n=48 participants.

Figure 2. Association between blood pressure measurements at home and in the study center. Abbreviations: R, Pearson's correlation coefficient; SBP, systolic blood pressure; DBP, diastolic blood pressure. Panel A shows the home blood pressure (mean of two consecutive measurements in both morning and evening at day 2, 3 and 4, x-axis) and corresponding study center blood pressure measurements (mean value of two consecutive measurements, y-axis) for each participant. Panel B shows the agreement between study center and home systolic and diastolic blood pressure measurements.

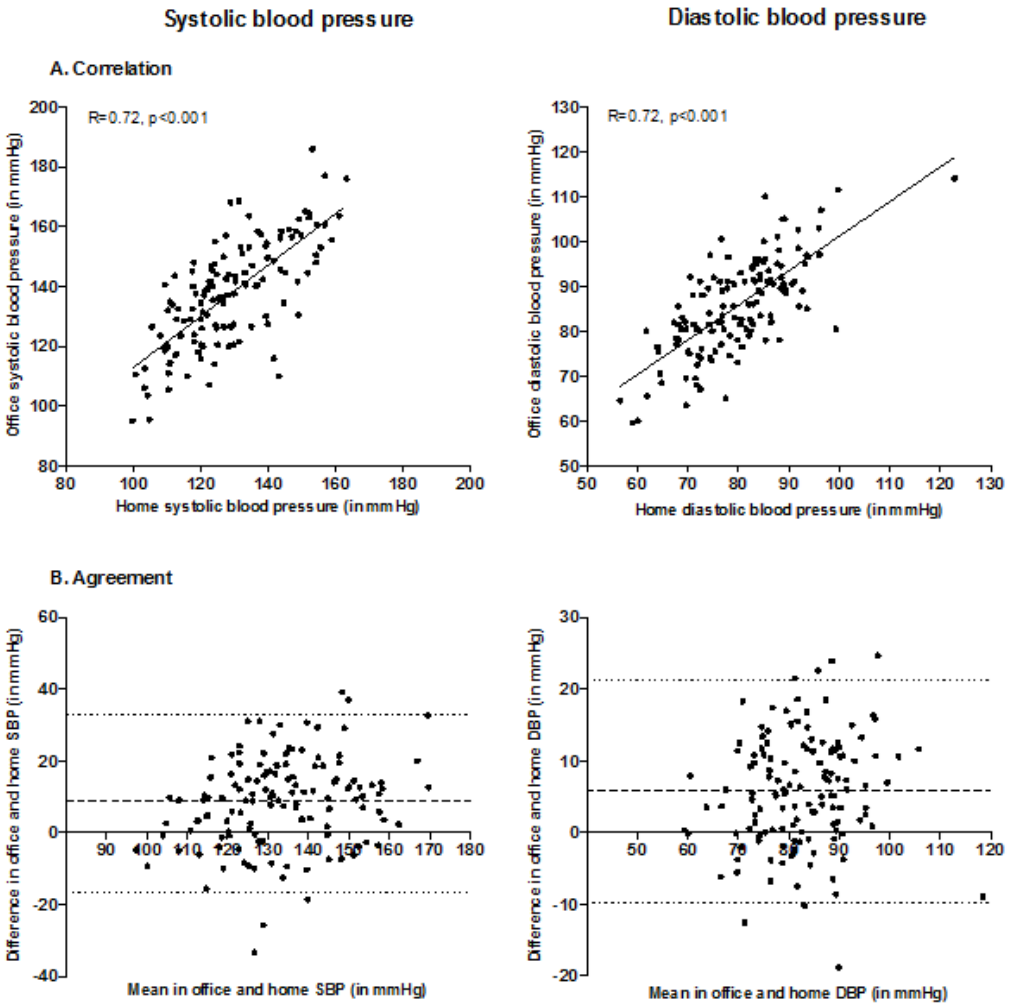
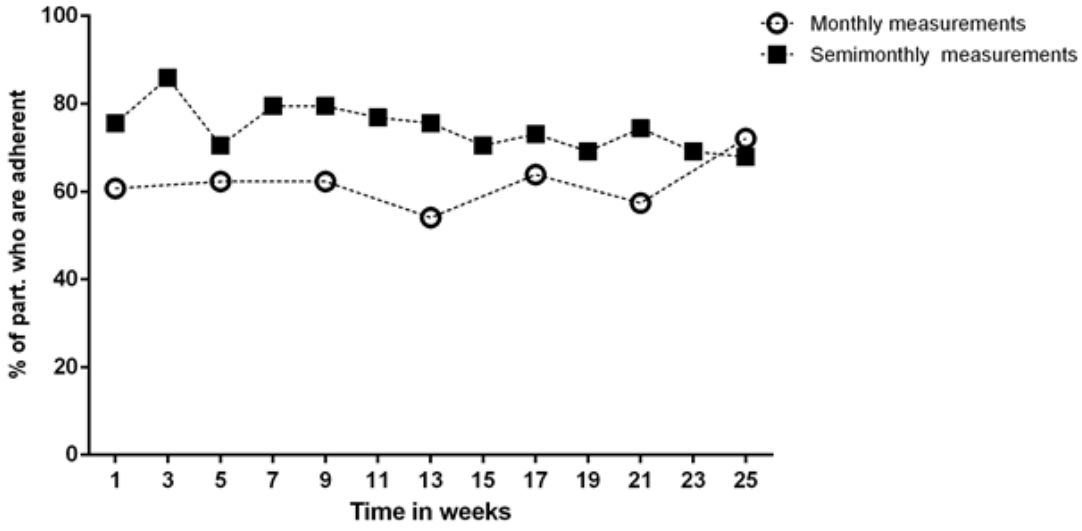


Figure 3. Adherence of participants to monthly and semi-monthly measurement protocol. Data represent the percentage of participants who are adherent to perform the expected blood pressure measurements.



Discussion

Principal Findings

This proof-of-principle study, in which we evaluated the feasibility of home blood pressure measurements during a 6-month intervention period using mobile phone-assisted technology, has 3 main findings. First, study center and home blood pressure were highly correlated, although blood pressure measured at the study center was systematically higher when compared with home blood pressure. Second, adherence of all participants to perform blood pressure measurements was high and persisted during 6 months with better adherence in participants measuring semimonthly compared with participants who performed monthly measurements. Third, in participants who were referred to their GP because of a high blood pressure, systolic and diastolic blood pressure decreased significantly during the study, especially for those who started medication.

Our finding that systolic and diastolic blood pressure at the study center was systematically higher when compared with home blood pressure measurements is in line with previous literature [22]. A well-known explanation for this is the "white-coat effect," meaning that blood pressure is higher because of stress and anxiety that patients experience during a clinical setting [22,23]. Literature shows that home blood pressure measurements, instead of office or clinic blood pressure measurements, are in fact a stronger prognostic indicator of cardiovascular events and even have their own (lower) reference values [12-14]. A participant-level meta-analysis including 5008 participants (mean age 57 years, not treated with antihypertensive medication), showed that in participants with an optimal office blood pressure (<120/<80 mm Hg), a 10-mm Hg higher systolic home blood pressure increased the risk of any cardiovascular event by nearly 30% [12]. In addition, previous studies on cost-effectiveness show that compared with usual care, home blood pressure monitoring is very useful for reducing health care costs. In view of the low burden of measuring and established treatment options, home blood pressure monitoring could therefore be an important strategy to further prevent cardiovascular complications, especially in people at risk [13].

Previous studies on adherence to perform home blood pressure measurements show similar results to our findings [17,24]. In a study on telemonitoring including 213 hypertensive patients, who were asked to measure their blood pressure at least 6 times a week during 6 months, mean adherence was 73% [17]. Another study including only patients with heart failure (mean age 61 years) showed adherence of 55% [24]. Furthermore, in this study, we found that participants using the semimonthly measurement protocol showed higher adherence compared with participants using the monthly measurement protocol. A possible explanation could be that the fact that participants received a reminder twice a month (instead of once a month), might have kept participants more engaged in the study and therefore increased their adherence [19]. Furthermore, the burden of measuring for 1 day every 2 weeks may have been perceived lower than measuring during 2 consecutive days, albeit with monthly intervals.

Home-based blood pressure measurements using mobile phone-based technology may have several potential opportunities. First, other parameters derived from repeated blood pressure measurements, can easily be calculated, especially in a home-based setting. An example of such a parameter is blood pressure variability, of which we recently showed its association with cognitive decline [25]. Second, the combination with other parameters and measurements may reveal additional targets for blood pressure control. Physical activity, sleep, and other lifestyle factors can be measured using a mobile phone. This offers the potential for interventions, for instance aimed at increasing physical activity, that also beneficially affect blood pressure. The iVitality platform offers the opportunity to assess these lifestyle factors. Third, mobile phone-based technology might be a cost-effective alternative in the control of hypertension. It was previously shown that ambulatory blood pressure monitoring as a diagnostic strategy for hypertension saves costs, mainly because additional costs from ambulatory monitoring are counterbalanced by cost savings from better targeted treatment [26]. As mobile phone-based technology only requires a standard blood pressure monitor, which is much cheaper when compared with an ambulatory blood pressure monitor, we believe it has the potential of saving health care costs.

In our study, blood pressure was lower at the end of follow-up when the participant was referred to the GP because of a high blood pressure at baseline. There are 2 possible explanations for this finding. First, the decrease in blood pressure may be the result of regression to the mean. This phenomenon occurs when repeated measurements tend to be followed by measurements that are closer to the mean. Although our baseline measurements were defined on repeated blood pressure measurements, it is still expected that the mean blood pressure during follow-up will go down, owing to regression toward the mean. Second, it may reflect a true effect of monitoring and subsequent treatment of blood pressure. Blood pressure lowering interventions by the GP and higher awareness of participants may all have contributed to a lower blood pressure. Although the fact that the effect on blood pressure was highest in those who initiated medication suggests the second explanation, we have not collected enough information on interventions in this proof-of-principle study to draw definite conclusions. An adequately powered randomized controlled trial may help to establish the effects of the interventions.

For this proof-of-principle study, we selected highly motivated participants with a parental history of dementia. This may have introduced a selection bias toward better adherence and treatment effects, which reduces the external validity for other, broader defined populations. The strength of this study is that mobile phone technology was used to collect study data on blood pressure. This innovative method reduces the need for face-to-face contact and stimulates self-management. Now that this proof-of-principle study is promising, broader and larger populations can be included in future studies.

Conclusions

This proof-of-principle study demonstrates that mobile phone-assisted technology can be used as a reliable and

promising method to measure blood pressure at home during a 6-month period. This provides a possibility for implementation in large-scale studies and can potentially lead to blood pressure reduction and eventually reduction of cardiovascular disease.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Baseline characteristics of iVitality participants, by protocol.

[PDF File (Adobe PDF File), 27KB - mhealth_v4i2e67_app1.pdf]

Multimedia Appendix 2

Adherence of participants to monthly and semimonthly measurement protocol (all participants included).

[PDF File (Adobe PDF File), 58KB - mhealth_v4i2e67_app2.pdf]

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Original Paper

Diet and Physical Activity Apps: Perceived Effectiveness by App Users

Qing Wang[1], MSc; Bjørg Egelandsdal[1], PhD; Gro V Amdam[2,3], PhD; Valerie L Almli[4], PhD; Marije Oostindjer[1], PhD

[1]Department of Chemistry, Biotechnology, and Food Science, Norwegian University of Life Sciences, Aas, Norway

[2]Department of Ecology and Natural Resource Management, Norwegian University of Life Sciences, Aas, Norway

[3]School of Life Sciences, Arizona State University, Tempe, AZ, United States

[4]Nofima AS, Aas, Norway

Corresponding Author:
Qing Wang, MSc
Department of Chemistry, Biotechnology, and Food Science
Norwegian University of Life Sciences
1430 Aas
Norway
Phone: 47 67 23 25 74
Fax: 47 64 96 50 01
Email: qing.wang@nmbu.no

Abstract

Background: Diet and physical activity apps are two types of health apps that aim to promote healthy eating and energy expenditure through monitoring of dietary intake and physical activity. No clear evidence showing the effectiveness of using these apps to promote healthy eating and physical activity has been previously reported.

Objective: This study aimed to identify how diet and physical activity (PA) apps affected their users. It also investigated if using apps was associated with changes in diet and PA.

Methods: First, 3 semi-structured focus group discussions concerning app usability were conducted (15 app users and 8 nonusers; mean age 24.2 years, SD 6.4), including outcome measures such as motivations, experiences, opinions, and adherence. Results from the discussions were used to develop a questionnaire. The questionnaire, which contained questions about behavior changes, app usage, perceived effectiveness, and opinions of app usability, was answered by 500 Norwegians, with a mean age of 25.8 years (SD 5.1).

Results: App users found diet and PA apps effective in promoting healthy eating and exercising. These apps affected their actions, health consciousness, and self-education about nutrition and PA; and were also a part of their social lives. Over half of the users perceived that apps were effective in assisting them to eat healthily and to exercise more. Diet apps were more effective when they were frequently used and over a long period of time, compared to infrequent or short-term use (P=.01 and P=.02, respectively). Users who used diet and PA apps, perceived apps as more effective than users who only used one type of app (all P<.05). App users were better at maintaining diet and PA behaviors than nonusers (all P<.05). Young adults found apps fun to use, but sometimes time consuming. They wanted apps to be designed to meet their personal expectations.

Conclusions: App usage influenced action, consciousness, self-education about nutrition and PA, and social life. It facilitated maintaining a healthy diet and exercising more. Diet and PA apps of the future can be further strengthened by being tailored to meet personal needs.

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KEYWORDS

diet app; physical activity app; perceived effectiveness; behavioral changes

Introduction

Since the mainstream adoption of smartphones during the last decade, consumers have since had easy access to a tremendous amount of health information through websites, social media, and health apps [1]. Health apps provide information to users whenever and wherever they want, and are tools for users who have a goal to improve their health. Diet apps and physical

activity (PA) apps are 2 types of health apps that aim to promote healthy eating and increased energy expenditure through monitoring dietary intake and PA. Using apps to affect eating behavior and PA behavior can be explained by the theory of planned behavior [2,3]. This theory shows that behavioral intention (eg, healthy eating, exercising) is driven by 3 constructs: attitudes towards the behavior, perceived behavioral control, and subjective norms. Attitudes are users' positive or negative evaluations of self-performance of the behavior. Perceived behavioral control is users' perceived ease or difficulty of performing the behavior. Subjective norms are users' perceptions of the behavior. Using apps may influence users' attitudes towards healthy eating or exercising, and it may relieve difficulties related to users engaging in healthy eating and exercise.

Many different types of diet and PA apps exist in app stores on different platforms. Diet/caloric intake apps and PA apps (fitness/training) are among the most popular in the "health and wellness" categories in app stores [4]. A diet app typically requires users to manually register what they eat each day. It converts food consumption into nutrition intake, summarizes results in plots and graphs, compares results with nutrition goals, offers nutrition and dieting information, and allows users to add their social network [5]. A PA app typically has GPS tracking to record physical activities, such as walking, jogging, and cycling. It also accurately records duration, frequency, and intensity of activities through an integrated gyroscope and/or accelerometer [6,7]. In addition, it calculates calorie expenditure, summarizes performance trends over time periods, and allows users to share their performance with friends on social networks.

Up to now, studies on diet and PA apps have evaluated the content of these apps and whether they were guided by relevant theory, or followed nutritional recommendations [8-10]. More research and evaluation is needed to show the perceived effectiveness of using these apps on healthy eating or increase in PA [11,12]. One approach is to evaluate how effective apps are from the users' point of view, and if they believe that app usage in general, independent of their detailed construction, will actually result in an intended behavior. Perceived effectiveness has been used for app evaluation [5]. It presents the effectiveness of the information system (perceived by the users [13]). This perceived effectiveness, thereby, reflects the user's self-assessment, and does not necessarily reflect actual effectiveness [14]. In general, previous studies evaluated health behavior change by using apps through qualitative methods [15] or only focused on one kind of app [16,17]. This study included both diet and PA apps, and evaluated perceived effectiveness through both qualitative and quantitative methods.

The objectives of this study were to identify how users perceive that they are affected by app use, and to investigate whether the use of apps was associated with improved diet and PA. Outcomes would indicate the potential of diet and PA apps for improving health.

Methods

This study used a combination of qualitative and quantitative methods. Three semi-structured focus group discussions were conducted with 15 app users (2 groups) and 8 nonusers (1 group), with a mean age of 24.2 years (SD 6.4). Participants discussed motivations for, experiences with, opinions about, and adherence to using health apps. The discussion results were summarized for a number of key topics, which were transformed into a questionnaire. The resulting questionnaire (Multimedia Appendix 1) was answered by 500 Norwegians, with a mean age of 25.8 years (SD 5.1).

Focus Group Discussions

Participants were students and staff at the Norwegian University of Life Sciences. They were recruited by email, and participated voluntarily. Selection of participants aimed to obtain a sufficient sample size of both app users and nonusers. Two focus group discussions with 2 male app users and 13 female app users, with an average age of 22.3 years (SD 7.3), were conducted and lasted 1.5 hours each. One focus group discussion with 6 male nonusers and 2 female nonusers, with a mean age of 24.8 years (SD 4.2), was conducted and lasted 1 hour. Female app users showed a higher interest in participating in focus group discussions, so there were more female app users than male app users in the focus groups. The 23 participants had 15 different university majors and lived in Akershus County and Oslo, near the university. Participants received monetary compensation for their participation (NOK 300/US $36). An experienced moderator led all 3 focus group discussions. In addition, an observer was present to take notes. The sessions were videotaped after consent was obtained from the participants.

Focus group discussions started with a general discussion about being healthy. Participants talked about methods they used to check health information and how they used health-related apps on a mobile phone, tablet, or computer. App operating systems were almost exclusively Android and iPhone OS. Users shared app usage motivation, goals, experiences, what they considered to be apps' pros and cons, and expectations for future apps. Nonusers shared personal opinions about health apps, reasons and barriers for not using apps, and expectations for future apps. This completed the discussion of whether using health apps could help people keep healthy, and how to adapt future apps to meet the needs of users.

Focus group discussions were transcribed and translated from Norwegian to English. Key topics were defined through indexing and categorizing [18]. The key topics included duration of use, adherence to using apps, goals, motivations, perceived effectiveness, and barriers for using apps. Two types of health apps were mentioned most frequently: diet apps and PA apps. An app questionnaire was developed based on the key topics derived from the focus group discussions, focusing on diet and PA apps only.

App Questionnaire

A cross-sectional Web-based questionnaire (Multimedia Appendix 1), aimed to assess dietary and PA changes and app usage among Norwegian young adults, was distributed in April 2015 through a market analysis company (Faktum Markedsanalyse AS, Oppegård, Norway). Participants were recruited by email from a national pool, and invited based on their age, which ranged from 18 to 35 years old; they had a

balanced sex distribution; and half were health app users, while half were nonusers. Individuals participated voluntarily. Personal attributes of the participants are shown in Table 1.

The first question in the questionnaire was "Have you used diet apps or PA apps on a mobile phone, tablet, or computer during the last 12 months?" Participants who had app usage experience were categorized as users, and those who did not were categorized as nonusers. The questionnaire consisted of 4 parts: (1) questions about changes in dietary behavior and PA during the last 12 months; (2) questions about using diet apps and/or PA apps during the last 12 months; (3) questions about opinions about using apps; and (4) general personal attribute questions. Users answered all 4 parts. Nonusers answered parts 1, 3, and 4. This questionnaire took 10-20 minutes to complete, depending on whether subjects were users or nonusers and how many types of apps they used.

The first part of the questionnaire contained 10 questions about dietary behavior and PA changes. This section was presented first in the questionnaire before the app questions, to prevent participants from being prompted about the effectiveness of apps. Diet-related changes included paying attention to calorie information, choosing healthier food (low-fat products and mineral water instead of sweetened beverages), cooking at home more than buying ready-made meals, and searching for food or cooking information on the Internet or in books/magazines. Physical activity-related changes included becoming a gym member, having activity competitions, sharing information about PA on social networks, and searching for activity-related information on the Internet or in books/magazines. Participants indicated whether they showed these behaviors before April 2014 (ie, 1 year before the questionnaire) and whether they showed these behaviors in April 2015 (ie, when they answered the questionnaire). Four questions asked participants about their goals and efforts to improve their diet and increase their PA in the last 12 months. A five-point scale (a lot less, a little bit less, about the same, a little bit more, a lot more) was used to measure their changes in food consumption and PA. Two questions examined weight loss goals and weight change during the last 12 months.

The second part of the questionnaire contained 12 questions. It first introduced general concepts of the apps and gave an example of a diet app ("myfittnesspal") and an example of a PA app ("Moves") [19,20]. Both apps were available for Android and iOS. Then, participants were asked about their duration and frequency of using the app in both the first and last month (if they stopped using the app before the questionnaire), goals (single choice) and motivations for using the apps, and perceived effectiveness of using diet and PA apps. The diet apps' effectiveness in assisting users to eat more low-fat alternatives in place of dairy products, eat more fruit and vegetables, eat less sausages, drink less sweetened beverages, eat less fast food, and choose healthier food products was evaluated. These diet changes were included based on the Nordic Nutrition Recommendations 2012, 5th edition [21]. The PA apps' effectiveness in assisting users to increase time spent on exercising, exercise more often, increase exercise intensity, and diversify their activities was measured using a 4-point scale (very effective, somewhat effective, slightly effective, or not effective).

The third part of the questionnaire contained 15 questions. A 7-point agree/disagree scale (disagree strongly, disagree moderately, disagree slightly, neutral, agree slightly, agree moderately, or agree strongly) was used to measure participants' opinions about apps and barriers for using those apps. Barriers included "it is hard to obtain information from apps," "it is time consuming to use apps," and "the apps do not fit personal expectations."

The fourth part of the questionnaire contained questions about gender, age, living region, weight, height, marital status, education, employment situation, yearly income, and food and health concerns. Food and health concerns were examined with the questions, "I am concerned about getting a lot of… (calories/fat/sugar) in my food" and "I am concerned about gaining weight" using a 5-point scale, from "I am extremely concerned" (5) to "I am not concerned at all" (1) [22]. Based on these questions, the survey had good reliability of responses (Cronbach alpha =.85).

The questionnaire was pretested by 6 food researchers and three master's students from the Department of Chemistry, Biotechnology, and Food Science, Norwegian University of Life Sciences. Small amendments were made to ensure that the questionnaire was clear, concise, and user-friendly.

Analysis of Questionnaire Data

App usage among app users was described by 4 factors from the questionnaire data: user type (users who used both diet app and PA apps; users who used only one type of apps); duration (0-1 months, 1-6 months, 6-12 months, or over 12 months); adherence (less frequently, same frequency, or more frequently); and goals. The goals for using diet apps were categorized into 4 types: to track food intake, to facilitate weight loss, to be healthy, and other goals. The goals for using PA apps were categorized into 4 types: to track PA, to do more PA, to facilitate weight loss, and other goals. The perceived effectiveness of using apps was categorized into effective, not effective, and do not know. The behavior changes were summarized into 4 categories (maintain, develop, give up, or never have the behavior) based on whether people had the behavior before April 2014 and whether they still had the behavior in April 2015. Food and health concern scores were calculated and participants were divided into 2 groups (high or low food, and health concern). Weight status (underweight, normal, overweight, or obese) was categorized based on body mass index (BMI) calculations from the questionnaire data.

All statistical analyses were performed using the statistical program R and R Commander version 3.2. Data were checked for model assumptions. Multinomial logistic models (MLM) identified associations between perceived effectiveness of using apps and app usage. The model was perceived effectiveness = user type (use both apps, or use only one type of apps) + duration + adherence + goals. MLM also identified associations between dietary behavior changes and app usage, association between PA changes and app usage, and association between weight change and app usage. The model was behavior changes

= user type (use both apps, use only diet apps, use only PA apps, or nonusers) + food and health concerns + weight status. Chi-square tests identified differences among app user groups. Associations between app usage and food consumption changes were identified by chi-square tests to explain weight changes among app users. Chi-square tests also identified associations between app usage and opinions about apps.

Table 1. Personal attributes of questionnaire participants (N=500).

Variable		%
Sex	Male	50.0
	Female	50.0
BMI [a]	Underweight (<18.5)	4.4
	Normal weight (18.5-24.9)	57.9
	Overweight (25-29.9)	24.0
	Obese (>30)	13.8
Living region	Northern Norway	8.7
	Mid Norway	13.3
	Western Norway	28.0
	Southern Norway	8.5
	Eastern Norway	41.7
Employment situation	Employed for wages	45.4
	Self-employed	3.8
	Unemployed	5.2
	Staying at home	3.4
	Student	35.6
	In the military	1.2
	Unable to work	5.4
Food and health concerns	High concern about food and health	16.8
	Low concern about food and health	83.2
Highest education	Primary school	13.2
	Secondary school	47.0
	College or university up to bachelor	28.2
	College or university up to master or PhD	11.6
Yearly income	0-200,000 NOK[b]	44.6
	200,000-400,000 NOK	26.2
	400,000-600,000 NOK	18.0
	600,000-800,000 NOK	6.0
	800,000-1,000,000 NOK	1.8
	>1,000,000 NOK	3.4
Marital status	Not married, without children	59.2
	Not married, with children	6.6
	Married or domestic partnership, without children	16.2
	Married or domestic partnership, with children	15.0
	Separated/Divorced/Widowed, without children	1.4
	Separated/Divorced/Widowed, with children	1.6

[a] BMI: body mass index

[b] NOK: Norwegian Kroner

Results

Focus Group Outcomes: A Model of Apps' Effects on Users

A model was summarized from the focus group discussions (Figure 1). It showed the influences of apps on users, according to the focus groups, categorized into 4 themes. Overall, apps offered an overview of how much one ate and exercised. For instance, diet app users obtained nutritional information about their daily consumptions of calories, carbohydrates, fat, and protein. These apps summarized and evaluated users' food intake. For example, one user said the following:

> *The app told me if I ate too few carbs relative to fat or protein intake.* [Female, 21 years]

Thus, by knowing their nutritional intake, users could adjust their eating to reach their goal of a balanced diet. Meanwhile, through this process, users gained experience and knowledge of nutrition and healthy eating. Using apps influenced self-assessment of diet, PA, and consciousness. Some users reported that they felt good about themselves because of their app usage, while other users felt stressed about using diet apps, mainly because it was time-consuming to register all the food items they consumed. Users felt that using apps could lead to higher awareness of the nutritional content of food, and higher awareness of and motivation for healthy eating and exercising. There were 2 examples given by users, who summarized the functions of diet and PA apps:

> *[You get] inspiration, information, [and] motivation to make healthier choices and confirmation that you have made the right choices, and guidance and tips about new food.* [Female, 19 years]

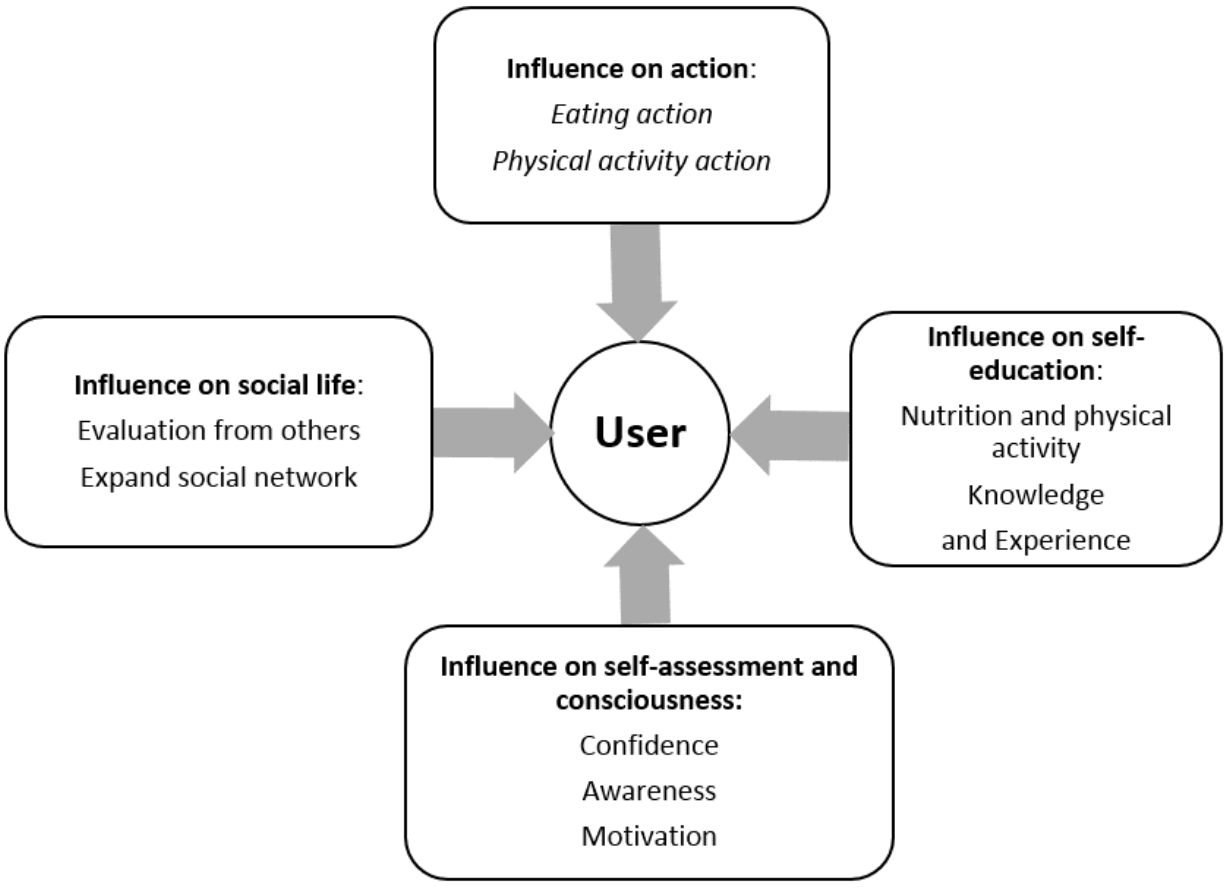
> *I have used an exercise app to get an overview of my activity. I used it to get some graphs and so on. It was motivating.* [Male, 24 years]

Influence on social life was another key point in the discussion. Users received positive or negative feedback from their friends or family. They could easily share the outcomes from apps on the Internet, especially those from the PA apps.

> *Results of training are fun to share.* [Male, 24 years]

Users could also be enrolled in a social network using apps, such as weight loss or dieting groups. They could either make new friends or strengthen relationships with old friends or family. Sharing diet or exercise outcomes on the Internet became one important motivation for participants to continue using apps.

Figure 1. Qualitative influences perceived by app users based on focus groups. Four themes were summarized from focus group discussions.



Questionnaire Outcomes: Perceived Effectiveness of Using Diet Apps

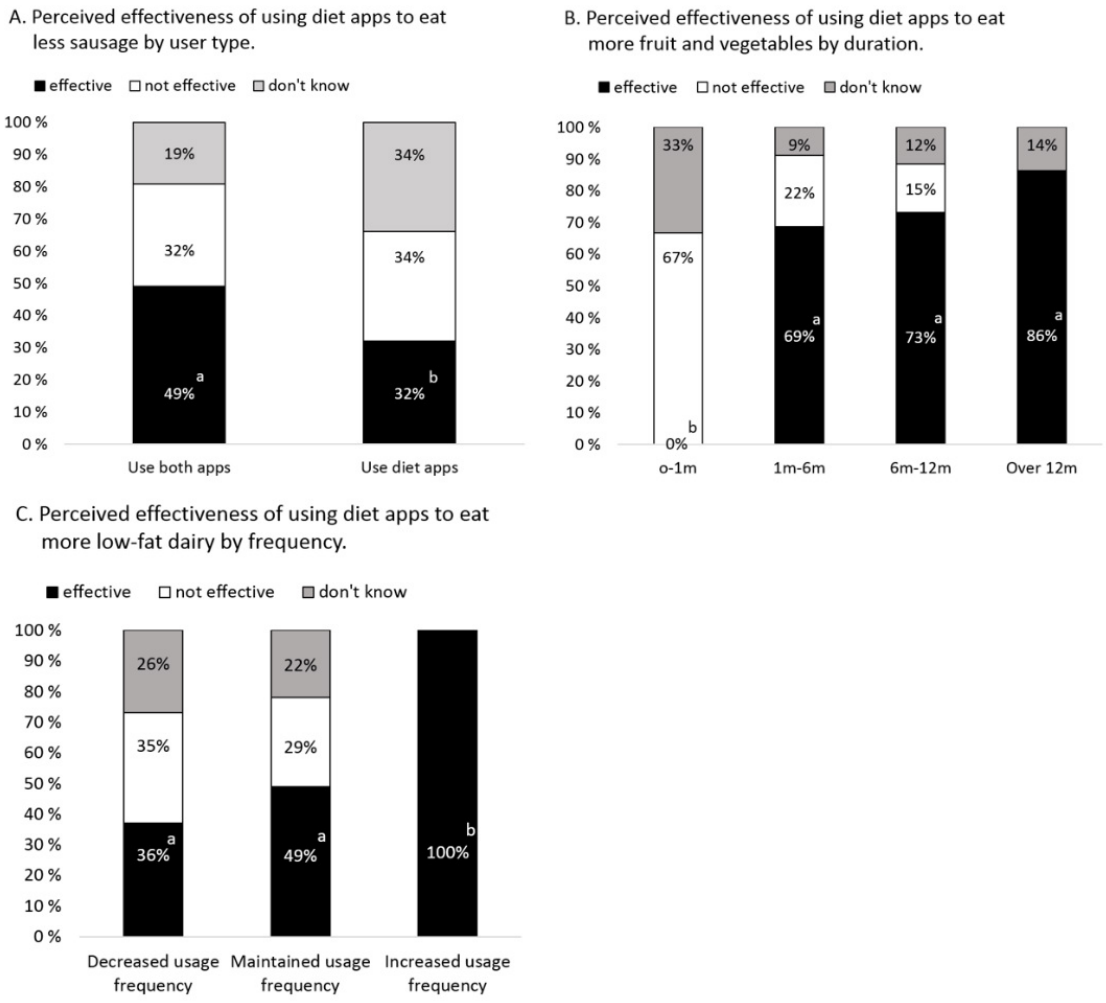
Overall, 186 diet app users and 192 PA app users answered the questionnaire, among whom 128 used both diet and PA apps. In general, diet and PA app users felt that apps were effective to facilitate their healthy food intake and activities. More than half of the diet app users felt that diet apps effectively assisted them to eat more fruit and vegetables (133/186, 71.5%), eat less fast food (117/186, 62.9%), choose healthier food products (117/186, 62.9%), and drink less sweetened beverages (106/186, 57.0%). Nearly half of diet app users found diet apps effective in assisting them to eat more low-fat dairy products (91/186, 48.9%) and less sausages (88/186, 47.3%). The majority of PA app users felt that PA apps effectively assisted them to exercise more often (144/192, 75.0%) and increase the intensity of exercises (139/192, 72.4%). More than half of the PA app users found that PA apps were effective in assisting them to increase time spent exercising (129/192, 67.2%) and diversify activities (106/192, 55.2%).

Perceived Effectiveness of Diet Apps Influenced by User Type, Duration, and Adherence

User type, duration, and adherence influenced perceived effectiveness of eating less sausages (P=.03), eating more fruit and vegetables (P=.01), and eating more low-fat dairy (P=.02), respectively. Goals did not influence perceived effectiveness. App usage, duration, adherence, and goals did not influence users' perceived effectiveness of diet apps for choosing healthier food products, drinking less sweetened beverages, or eating less fast food.

Users of both diet and PA apps had a higher probability of reporting that diet apps effectively assisted them to eat less sausages than users who only used diet apps, χ^2_1=4.2, P=.04 (Figure 2, Part A). Duration was associated with perceived effectiveness of eating more fruit and vegetables. Users who used diet apps for more than one month had a higher probability of reporting that apps were effective in assisting them to eat more fruit and vegetables than users who used diet apps for less than one month (all P<.05, Figure 2, Part B). Adherence was associated with perceived effectiveness of eating more low-fat dairy. Diet app users, who had increased the frequency of using apps in the past 12 months, had a higher probability of reporting that apps were effective in assisting them to eat more low-fat dairy than users who decreased their app usage frequency, χ^2_1=11.1, P<.001, or users who maintained the same frequency of using apps, χ^2_1=7.4, P=.007 (Figure 2, Part C).

Figure 2. Percentages of different diet app user categories and their evaluation of the effectiveness of using diet apps to assist their food intake.

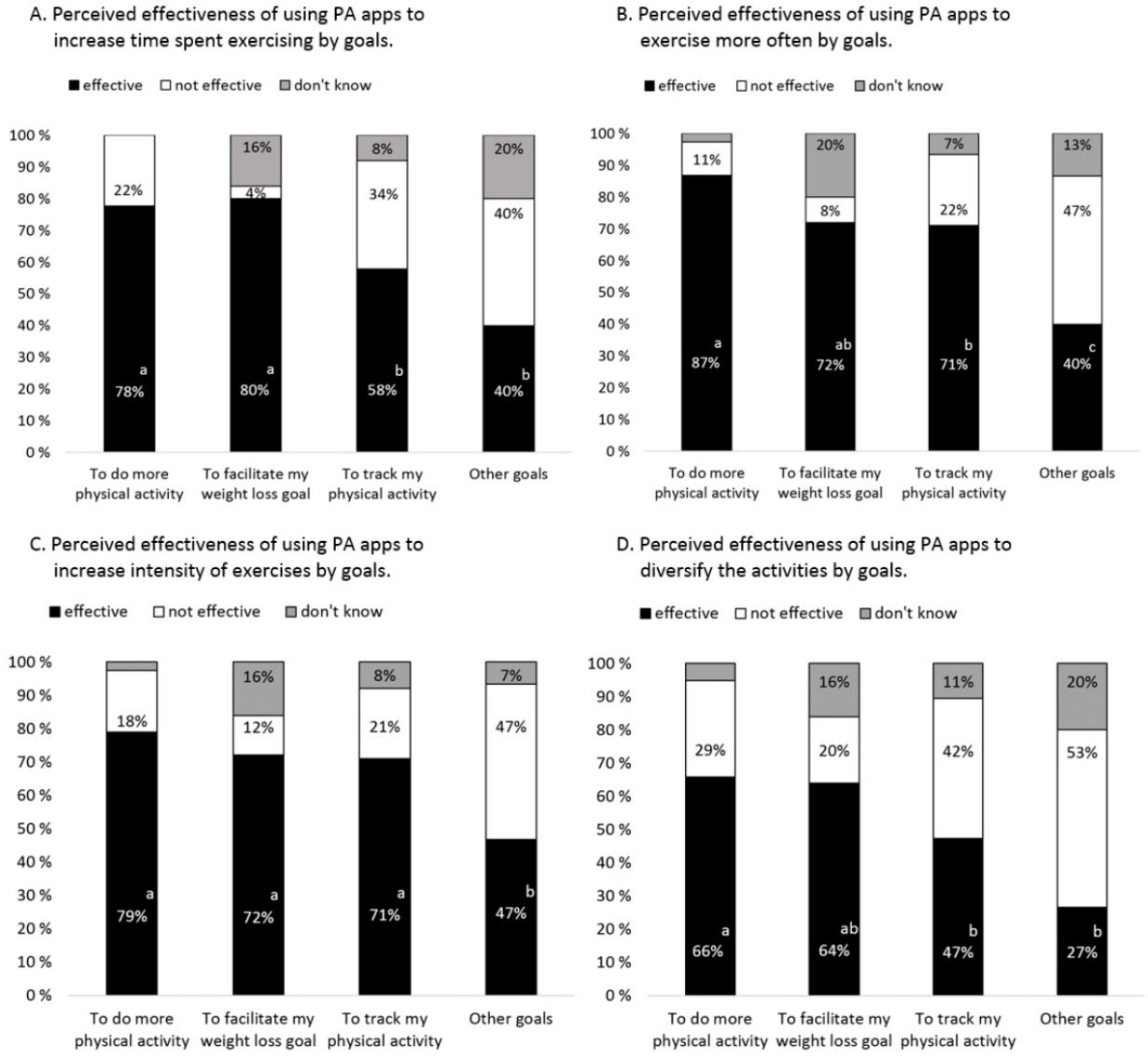


Perceived Effectiveness of Using PA Apps Influenced by App Usage and Goals

App usage influenced the perceived effectiveness of diversifying physical activities (*P*=.003). Duration of and adherence to using apps did not influence users' perceived effectiveness of PA apps. Goals influenced perceived effectiveness for increasing time spent exercising, exercising more often, increasing intensity of exercises, and diversifying activities (all *P*<.05).

App usage was associated with perceived effectiveness of diversifying activities. More users of both diet and PA apps reported that PA apps effectively assisted them to diversify activities than did those who used only PA apps, χ^2_1=12.2, *P*<.001. Goals were associated with perceived effectiveness of using PA apps (Figure 3). PA app users with a goal to do more PA or to lose weight had a higher probability of reporting that apps were effective in assisting them to increase time spent on exercising, than did users who only wanted to track their PA (*P*=.009 and *P*=.046, Figure 3, Part A). PA app users who had a goal to do more PA had a higher probability of reporting that apps were effective in assisting them to exercise more often or to diversify their activities than users who had a goal to track their PA (both *P*=.02) or who had other goals (*P*<.001 and *P*=.005, Figure 3, Parts B and D). More PA app users who had a goal to do more PA, to reach a weight loss goal, or to track PA, reported that apps were effective in assisting them to increase the intensity of exercises than did users who had other goals (all *P*<.05, Figure 3, Part C).

Figure 3. Percentages of PA app users with different goals and their evaluation of the effectiveness of using PA apps to assist their physical activities.



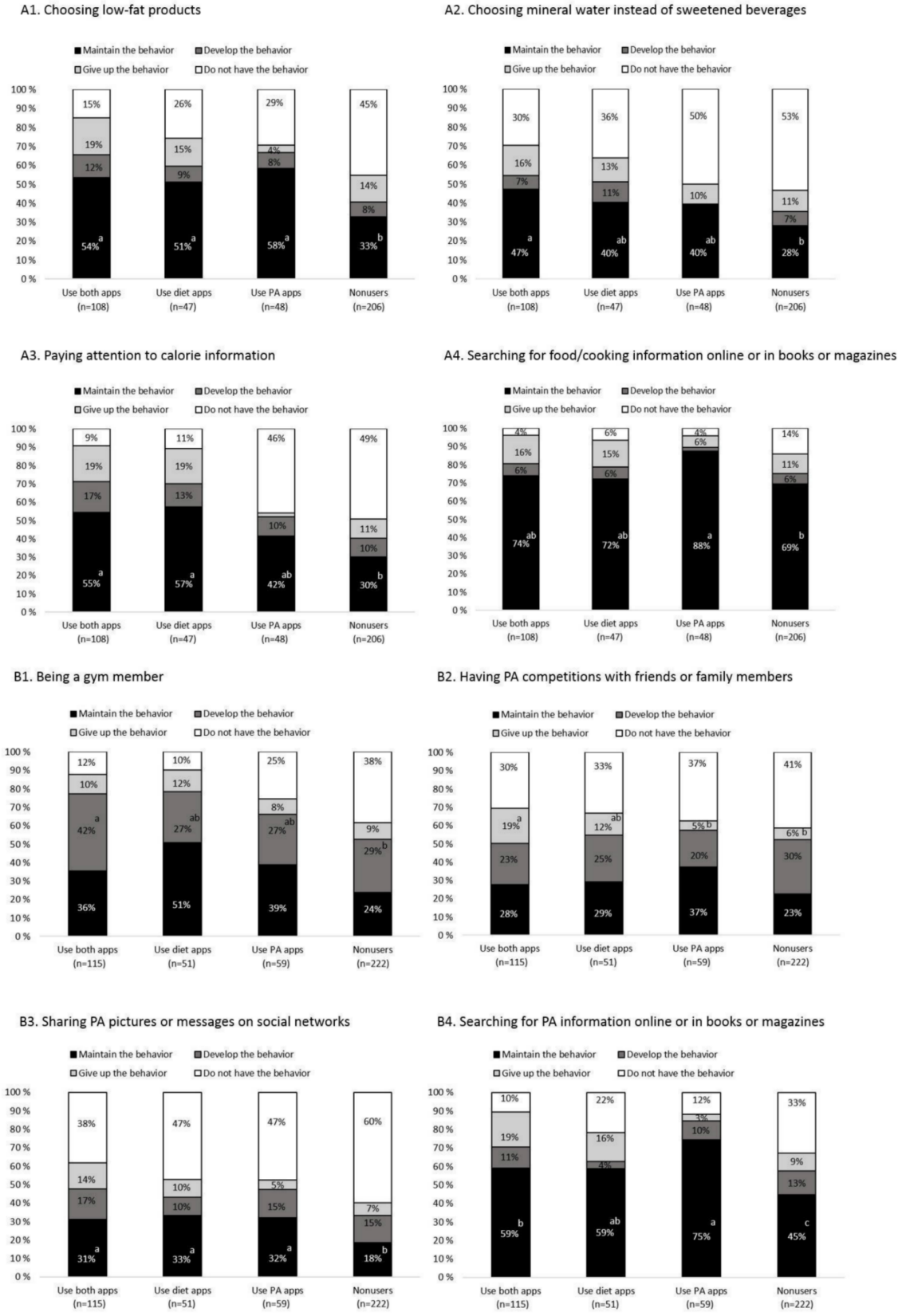
Dietary and Physical Activity Behavior Changes and Weight Change Associated With App Usage

Dietary Behavior Changes Influenced by App Usage

App usage was associated with the following dietary behavior changes: choosing low-fat products, choosing mineral water instead of sweetened beverages, paying attention to calorie information, and searching for information about food and cooking (all $P<.05$, Figure 4A). App usage did not influence the behavior change of cooking at home instead of buying ready-made meals. Food and health concerns were associated with paying attention to calorie information and cooking at home instead of buying ready-made meals ($P<.001$ and $P=.03$). Weight status was not associated with dietary behavior changes (all $P>.15$).

App users had a higher probability of maintaining the behavior of choosing low-fat products instead of ordinary products compared to nonusers (all $P<.05$, Figure 4A1). Users of both diet and PA apps had a higher probability of maintaining the behavior of choosing mineral water instead of sweetened beverages compared to nonusers ($\chi^2_1=11.4$, $P<.001$, Figure 4A2). Diet app users—who used both diet and PA apps or only diet apps—had a higher probability of maintaining the behavior of paying attention to calorie information than nonusers (both $P<.001$, Figure 4A3). Those who used only PA apps had a higher probability of maintaining the behavior of searching for information about food or cooking on the Internet, or in books or magazines, than nonusers ($\chi^2_1=6.4$, $P=.01$, Figure 4A4).

Figure 4. Percentages of dietary behavior change and physical activity behavior change among different participants (use both apps, use diet apps, use PA apps, and nonusers). A1-A4. Dietary behavior changes. B1-B4. Physical activity behavior changes.



Physical Activity Behavior Changes Influenced by App Usage

App usage was associated with changes in PA including becoming a gym member, having competitions with friends and family members, sharing pictures or messages related to exercises on a social network, and searching for PA information on the Internet or in books or magazines (all $P<.05$, Figure 4B). Food and health concerns, as well as weight status, were associated with the PA behavior change of having competitions with friends or family members ($P=.009$ and $P=.02$). Food and health concerns, and weight status, were not associated with the other PA behavior changes.

Users of both diet and PA apps had a higher probability of becoming gym members than nonusers ($\chi^2_1=7.2$, $P=.007$, Figure 4B1), and a higher probability of giving up having PA (eg, running, skiing) competitions with friends or family members than nonusers ($\chi^2_1=6.3$, $P=0.01$) and those who only used PA apps ($\chi^2_1=13.1$, $P<.001$, Figure 4B2). They also had a higher probability of continuing to share pictures or messages related to their exercises on a social network than nonusers ($\chi^2_1=7.1$, $P=.007$, Figure 4B3). Those who used only PA apps had a higher probability of continuing to search for PA information on the Internet, or in books or magazines, than those who used both diet and PA apps ($\chi^2_1=4.1$, $P=.04$) or nonusers ($\chi^2_1=16.8$, $P<.001$, Figure 4B4).

Weight Change Influenced by App Usage

App users and nonusers differed in their weight change ($P=.001$). Food and health concerns and weight status did not affect weight change. Those who used both diet and PA apps and those who used only diet apps had a higher probability of weight loss during the last 12 months compared to nonusers ($P<.001$ and $P=.01$) and users who used only PA apps ($P=.001$ and $P=.03$). Diet app users ate more fruit and vegetables and a lower total amount of food during the last 12 months compared to PA app users and nonusers ($P=.04$ and $P=.002$, respectively). There was no significant difference in low-fat food, processed meat, sweetened beverage, and fast food consumption between PA app users and nonusers (all $P>.1$).

Opinions About Apps

Both app users and nonusers provided their opinions about the apps (Table 2). In sum, 339 out of 500 participants (67.8%) thought that mobile phones, tablets, or computers were easy for them to use and they liked using them; and 319 out of 500 participants (63.8%) felt apps were not hard for them to understand. Half of the participants thought it was not hard to obtain information from apps, and only 143 out of 500 participants (28.6%) thought it was time consuming to use these apps. In total, 160 out of 500 participants (32.0%) felt it was fun to use apps.

Generally, the app users had positive opinions about using health apps. Their opinions were more positive than nonusers' perceptions of app usage. Comparing to nonusers, there were more app users who agreed with opinions that they were concerned about health, and so they wanted to use health apps and found it fun to use them (both $P<.001$). More app users disagreed with opinions that apps could not help them to be healthy, that it was hard to get information from apps, that it was time consuming to use apps, or that they could not find an app that fit their expectations, compared to nonusers (all $P<.001$).

Table 2. Opinions about apps—percentages of disagreement/agreement with nine statements about health apps (N=500).

Opinions	Disagree strongly	Disagree moderately	Disagree slightly	Neutral	Agree slightly	Agree moderately	Agree strongly
I like to use smartphones, tablets, or computers.	6.4%	3.8%	4.2%	17.8%	12.2%	15.8%	39.8%
It is easy for me to use smartphones, tablets, or computers.	3.6%	3.8%	3.4%	14.4%	9.4%	13.2%	52.2%
It is hard for me to understand how health-related apps work on smartphones, tablets, or computers.	37.0%	16.6%	10.2%	25.6%	6.2%	2.6%	1.8%
I am concerned about my health, so I want to use health-related apps.	28.8%	13.8%	7.4%	30.2%	12.0%	5.8%	2.0%
I think health-related apps cannot help me to be healthy.	14.8%	13.4%	18.0%	31.0%	9.2%	8.0%	5.6%
It is hard for me to get information from health-related apps.	17.2%	19.2%	13.6%	38.2%	7.6%	1.6%	2.6%
It is time consuming for me to use health-related apps.	11.2%	11.6%	15.2%	33.4%	18.0%	6.6%	4.0%
I find it fun to use health-related apps.	10.6%	7.6%	9.0%	40.8%	15.8%	11.6%	4.6%
I cannot find a health-related app that fits my expectations.	12.2%	9.2%	10.8%	48.4%	11.2%	4.8%	3.4%

Discussion

Principle Findings

This study suggests that users find diet and PA apps effective in promoting healthy eating and more exercise through effects on their actions, health consciousness, self-education about nutrition and PA, and social life. Apps were particularly effective when they were used frequently and over a long period (eg, more than 1 month). App usage was also associated with actual self-reported behavior, particularly maintenance of healthy behaviors, and also, depending on the goal, adoption of new behaviors in the case of PA apps.

In the focus group, users and nonusers discussed and evaluated the apps' influence on diet and PA. Users reported that using apps influenced eating and exercising. Based on responses to the questionnaire, they perceived that they ate healthier foods and exercised more when using apps. A previous qualitative study showed that users considered an app's ability to record and track behavior and goals as valuable [23]. By recording and tracking food intake and physical activities, apps give feedback to users on how well they are doing in reaching their goals. One study reported that feedback significantly increased users' motivation to engage in PA [24]. Apps act as a reminder or evaluator for users. They also give suggestions and alternatives related to dieting and exercising that aim to help users achieve their goals. In the focus group discussions, users felt more confident about themselves when they experienced success in healthy eating and increased exercising. Frequent use over time can result in positive evaluation of self-performance, and in response, an improved attitude towards the behavior (in this case healthier eating or increased exercising), particularly when the app has options to show users their progress over time. Increased knowledge and awareness, which often were brought up in the focus groups, can make it easier for users to perform a behavior, and thus increase perceived behavioral control. Users also experienced interactions between social networks and app usage, which may in turn affect social norms. They received both positive and negative comments and feedback from friends and family members, and sometimes even used apps together with friends, which facilitated sharing of outcomes. Based on the theory of planned behavior, using apps influenced all three constructs (attitudes towards the behavior, perceived behavioral control, and subjective norms), which strengthened the behavior intention. The stronger the intention, the more likely it was that users would execute a healthy behavior [25]. In this study, app users perceived that apps were effective in facilitating their food intake and activity. Results from this study showed that diet apps could be effective in promoting users to follow the Nordic Nutrition Recommendations, and PA apps could be effective in promoting users to increase duration, frequency, intensity, and diversity of exercise. Using apps strengthened users' intentions and behavior performance.

The findings of this study support the concept that app usage can expand eHealth literacy. eHealth literacy reflects people's ability to seek, find, understand, and appraise health information from electronic sources and apply that knowledge to make a health-related decision [26]. Users explored eHealth information through the apps. By seeking, understanding, and appraising eHealth information, they processed it to guide their actions. At the same time, limited eHealth literacy can preclude some populations from accessing health information. Prior research has shown that individuals' education, health status, and motivation influences eHealth literacy [27]. Furthermore, younger and more educated people have higher eHealth literacy than their counterparts [28]. However, in general, users find apps easy and convenient to use [29,30]. These findings coincide with those of this study, in that half of the survey population thought it was not hard to obtain information from apps.

Since using apps could strengthen behavioral intention and expand eHealth literacy, this study also examined whether using apps led to self-reported health behavior changes during the last 12 months. Health behavior change is a central objective of health promotion, and new health behaviors are often not maintained [31,32]. Results of the questionnaire showed that app usage was associated with maintenance of healthy behaviors. App users continued to choose low-fat products instead of high-fat alternatives and mineral water instead of sweetened beverages, and continued to look for diet-related and PA-related information more often than the nonusers. Using apps advanced self-regulation skills and ability, and supported users to engage in healthy behaviors [33]. In addition, over 66.7% (128 out of 192) of the app users used both diet and PA apps, and monitored both food intake and energy output. These individuals maintained health behaviors better than those who only used diet or PA apps. Future studies could provide details on the role of combined app usage in changing health behaviors, to give more specific advice.

In this study, there was no direct evidence showing a relationship between app users' perceived effectiveness of using apps and their actual health behavior changes. This study had a few examples showing a weak link between perceptions and behavior. For example, more than half of the app users perceived that PA apps effectively assisted them to be active; meanwhile, this group of people had a higher probability of becoming a gym member as an actual behavior. However, perceptions may not always match behaviors. The relationship between perceived effectiveness of using apps and actual behavior change needs further evaluation.

Users reacted in various ways toward the apps. According to the questionnaire, 97 out of 500 participants (19.4%) agreed that they could not find an app that met their expectations. Further development of diet and PA apps could involve tailoring to match requirements on a personal or subgroup level, such as for teenagers, young adults, middle-aged adults, or older adults. These subgroups differ in knowledge, experience, health situations, and goals. Each user has individual needs, so personalization of apps is necessary. Tailoring apps to meet personal needs has been discussed and suggested in previous studies [23,34,35]. In this study, in the focus group discussions, some users complained that they had difficulty finding Norwegian brands and foods in diet apps, since most were not developed based on the Norwegian food market. Both users and nonusers mentioned that tailoring apps to fit personal interests would be a good idea for the future development of apps. Thus, users would benefit more if apps were tailored to their

expectations and personal needs. Meanwhile, since nonusers' perceptions of app usage were less positive than users in this study, tailoring apps to fit nonusers' needs may increase their interest in using apps.

This study evaluated perceived effectiveness and self-reported behavior changes associated with app usage through a questionnaire. It revealed the effects of apps on healthy eating and exercising; however, these effects were not validated in a randomized controlled trial. Future studies should evaluate the strengths of the reported effects in randomized controlled trials with adequately powered sample sizes. The sample population in this study may be a limitation, and larger sample sizes should be implemented in future work.

Conclusions

Using diet and PA apps influenced actions, consciousness, self-education about nutrition and PA, and social lives of users. App usage facilitated healthy eating and increased exercising, as well as the maintenance of healthy behaviors. The apps were considered fun to use; however, some (eg, dietary apps) were time-consuming. Future apps could be tailored to meet personal needs, and future studies could use app tracking data to measure actual food consumption and PA changes rather than perceived changes through self-reports.

Acknowledgments

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Conflicts of Interest

The authors have no declared conflicts of interest.

Multimedia Appendix 1

Study questionnaire.

[PDF File (Adobe PDF File), 272KB - mhealth_v4i2e33_app1.pdf]

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Abbreviations

PA: physical activity

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Original Paper

Using Mobile Apps to Promote a Healthy Lifestyle Among Adolescents and Students: A Review of the Theoretical Basis and Lessons Learned

Denise Jantine Dute[1], MSc; Wanda Jose Erika Bemelmans[1], PhD; João Breda[2], PhD

[1]National Institute for Public Health and Environment (RIVM), Bilthoven, Netherlands

[2]World Health Organization Regional Office for Europe, Noncommunicable Diseases and Life-Course, Copenhagen, Denmark

Corresponding Author:
Wanda Jose Erika Bemelmans, PhD
National Institute for Public Health and Environment (RIVM)
Antonie van Leeuwenhoeklaan 9
P.O. Box 1, 3720 BA
Bilthoven,
Netherlands
Phone: 31 30 2744297
Fax: 31 30 2744414
Email: wanda.bemelmans@rivm.nl

Abstract

Background: European adolescents and students tend to have low levels of physical activity and eat unhealthy foods, and the prevalence of overweight and obesity has increased, which poses a public health challenge. Mobile apps play an important role in their daily lives, suggesting their potential to be used in health-promoting strategies.

Objective: This review aimed to explore how mobile apps can contribute to the promotion of healthy nutrition, physical activity, and prevention of overweight in adolescents and students. For the apps identified, the review describes the content, the theoretical mechanisms applied, and lessons learned.

Methods: The databases Scopus, MEDLINE, Embase, and PsycINFO were searched for English-language publications from January 2009 to November 2013. Studies were included if (1) the primary component of the intervention involves an app; (2) the intervention targets healthy nutrition, or physical activity, or overweight prevention; and (3) the target group included adolescents or students (aged 12-25 years).

Results: A total of 15 studies were included, which describe 12 unique apps. Ten of these apps functioned as monitoring tools for assessing dietary intake or physical activity levels. The other apps used a Web-based platform to challenge users to exercise and to allow users to list and photograph their problem foods. For 5 apps, the behavioral theory underpinning their development was clearly specified. Frequently applied behavior change techniques are prompting self-monitoring of behavior and providing feedback on performance. Apps can function self-contained, but most of them are used as part of therapy or to strengthen school programs. From the age of 10 years users may be capable of using apps. Only 4 apps were developed specifically for adolescents. All apps were tested on a small scale and for a short period.

Conclusions: Despite large potential and abundant usage by young people, limited research is available on apps and health promotion for adolescents. Apps seem to be a promising health promotion strategy as a monitoring tool. Apps can enable users to set targets, enhance self‐monitoring, and increase awareness. Three apps incorporated social features, making them “social media,” but hardly any evidence appeared available about their potential.

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KEYWORDS

mHealth; mobile phones; behavior change; health promotion; physical activity; nutrition; overweight; adolescents and students

Introduction

The lifestyle of European adolescents and students poses a serious public health challenge. Adolescents and students tend to have low levels of physical activity and eat unhealthy foods. In addition, the prevalence of overweight and obesity within this group has increased in many countries. A study that monitored the physical activity of children and adolescents at ages 9, 11, 12, and 15 years found that physical activity levels decreased as children enter adolescence [1]. The Health Behavior in School-aged Children 2009/2010 survey showed that young people in Europe prevalently skip breakfast and consume increasing amounts of soft drinks and less amounts of fruits between ages 11 and 15 years [2]. Furthermore, the prevalence of overweight, including obesity, among 11-year-old European children ranged from 5% to more than 26% in some countries [2]. The annual overweight rates are increasing continuously, which demonstrates the need for public intervention [3].

Mobile apps seem to be promising tools to help people improve their health [4]. Apps are software applications that enable programs to run on smartphones. Because smartphones can be used anywhere and at any time, they can potentially reach many people and can offer good opportunities to contribute to health promotion and health protection. They can be particularly beneficial in reaching adolescents and students. In 2012, 56% of Dutch adolescents (12-15 years old) [5,6] and 78% of Dutch students (16-25 years old) owned a smartphone [7]. Young people and middle-aged adults use their smartphones more often than older adults. A total of 58% of Europeans aged 16-24 years use mobile Internet compared with 36% and 12% of the population aged 25-54 years and 55-74 years, respectively [8].

An interesting question is whether apps can be applied in health promotion for adolescents and students. Additionally, it would be beneficial to know how mobile apps can be used effectively in health promotion. So far, little research has been published about their effectiveness in health promotion [9]. Crutzen et al [10] found that Web-based interventions embedded in existing structures, such as health care or schools, are more effective compared with Web-based interventions alone. Furthermore, evidence indicates that effectiveness of health promotion interventions also depends on the extent to which they are based on theoretical mechanisms for changing behavior [11,12].

Theory-based interventions use one or more theories during their development [13]. Several theories have been proposed that can predict and explain human behavior. For example, the theory of planned behavior describes 3 factors, namely, attitude, subjective norm, and perceived behavioral control, that have an influence on an individual's intention to perform a given behavior [14]. Ajzen [14] stated that the stronger the intention to engage in a behavior, the more likely should be its performance. Another classic model is the transtheoretical model, the usefulness of which has been investigated for decades [15]. The model assesses an individual's readiness to adopt a new healthier behavior and describes strategies or processes to guide the individual through the stages of change, from precontemplation to action and maintenance.

Abraham and Michie [16] developed a taxonomy of 26 generally applicable behavior change techniques. The behavior change techniques are based on 6 behavior change theories: information-motivation-behavioral skills model, theory of reasoned action, theory of planned behavior, social cognitive theory, control theory, and operant conditioning. This taxonomy is useful in determining which techniques are applied in apps that are aimed at changing lifestyle [13] and hence to identify techniques that have been used with success, to develop better apps in the future, and to identify potential gaps in literature.

The purpose of this review was to provide insight into how mobile apps can contribute to the promotion of healthy lifestyles among adolescents and students. We provide an overview of apps that have been developed (also) for adolescents or students with the aim of improving health, by promoting healthy nutrition, physical activity, and preventing overweight and obesity. For the apps that have been identified, we describe which theoretical mechanisms were applied during the development of the apps, and we summarize the lessons learned.

Methods

Inclusion and Exclusion Criteria

Only publications written in English were included. Furthermore, studies were included if (1) the primary component of the intervention involves a mobile app and this mobile app is already developed; (2) the intervention targets healthy nutrition, or physical activity, or overweight prevention; and (3) the focus is on adolescents and students (aged 12-25 years). Studies that also included people outside this age range (eg, 18-30 years) were included because these studies could provide valuable information regarding the primary target group. The articles were read carefully for age-specific information. The inclusion criteria for healthy nutrition include, among others, eating more vegetables and fruits, reducing soft drink or increasing water consumption, and reducing snack consumption. The applied methodology of the studies, for example, to assess effectiveness, was not an inclusion criterion because this was not relevant for answering parts 1 and 2 of the research questions (ie, the overview of existing apps and their theoretical bases). For the third part, the lessons learned, this is of relevance, and we mention the research methodology in that section of the paper.

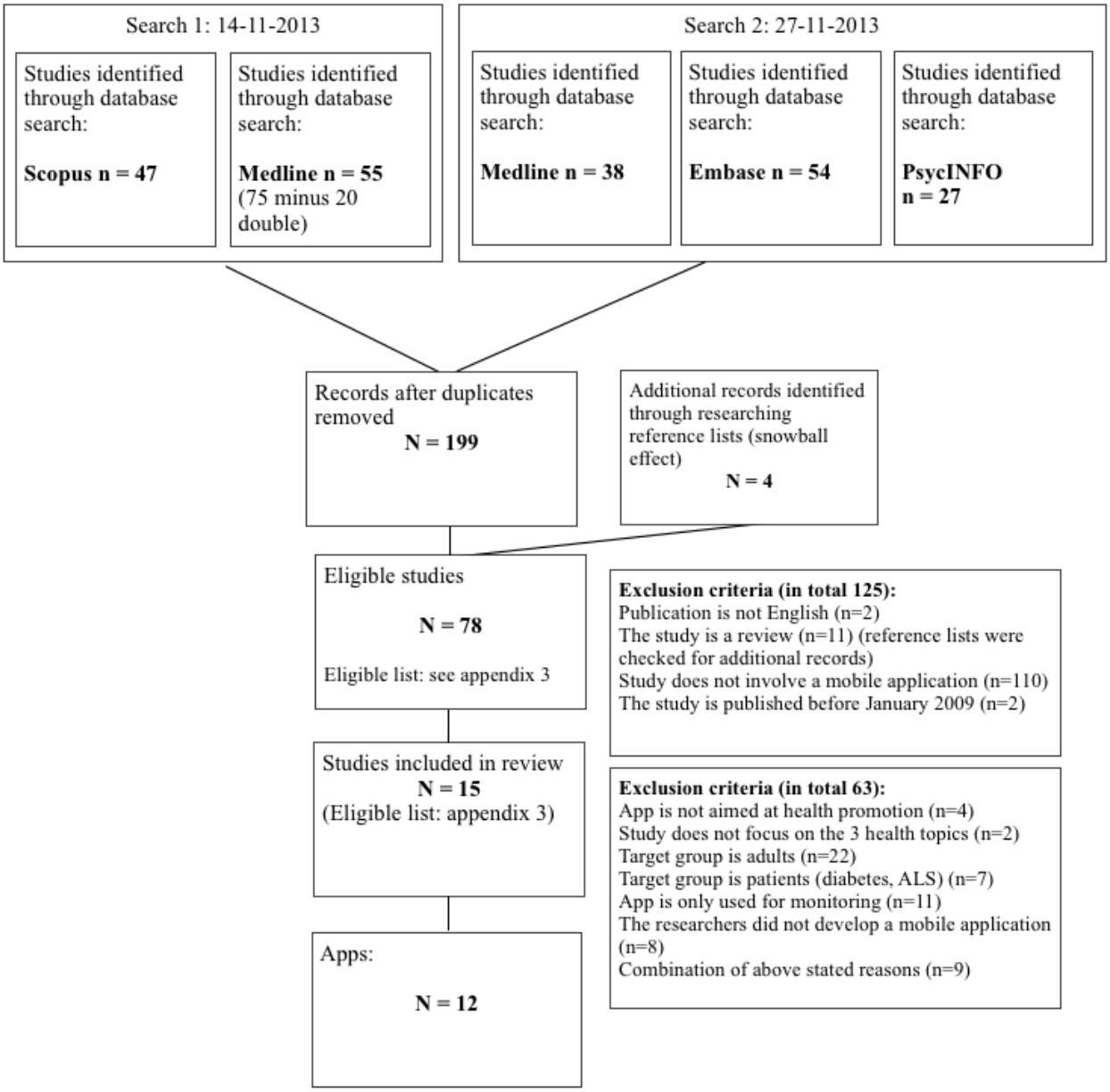
Studies were excluded if researchers did not develop the mobile app described, if researchers did not focus on mobile apps, or if the app was used for data collection for research purposes (monitoring). Studies were included when data collection was applied with the intention of changing behavior. For example, the app served as a tool that was meant to increase awareness, a relevant step during the process of changing behavior. Other exclusion criteria were apps developed for a specific group of people with a health-related condition (patients with congenital heart disease or diabetes) and studies that focused on other preventive health issues, such as sport injuries and alcohol abuse.

Search Strategy

The research databases Scopus, MEDLINE, Embase, and PsycINFO were searched for publications from January 2009

to November 2013 (Scopus and MEDLINE November 14, 2013; Embase, MEDLINE, and PsycINFO November 27, 2013). It was decided to include studies since January 2009 because the Apple App Store was opened in July 2008. For Scopus, the following search string was used: ((("mobile phone*" OR "smart phone*"OR "smart-phone*") AND ("app" OR "apps" OR "application")) AND (TITLE (physical* OR healthy OR overweight OR nutrition* OR exercise*))) AND (TITLE-ABS-KEY-AUTH (adolesc* OR young* OR school* OR teenager*)) AND (LIMIT-TO (DOCTYPE, "ar") OR LIMIT-TO (DOCTYPE, "re")). The following search terms were used for Embase, MEDLINE, and PsycINFO (November 27, 2013): smartphone (smart phone*, mobile phone*, game, games, gaming, mobile (all in title), phone, phones, android), exercise, sports, physical activity, food, body weight, nutrition, adolescent, young adult, youngster, teenage*, and mHealth. The extensive search strategy is shown in Multimedia Appendix 1. The first search in MEDLINE was slightly different from the second because it did not include the term game (games, gaming), fewer terms were used concerning health behaviors (sports, physical activity, nutrition), and it added the term telemedicine (Multimedia Appendix 2). These searches resulted in 199 unique studies (Figure 1). To obtain additional eligible studies, the reference lists of relevant studies and reviews were searched. As a result, 4 more studies were added. Figure 1 illustrates the search and selection process.

Figure 1. Search strategy.



Data Extraction and Synthesis

On the basis of title, 203 studies were screened. A total of 125 studies were excluded because they did not match the following criteria: the study was not written in English (n=2), the study was a review (n=11; reference lists were checked for additional studies), the article did not involve a mobile app (n=110), and the study was published before January 2009 (n=2). Thereafter,

abstracts and, in some cases, entire studies were read. Studies were excluded based on target group (adults n=22, patients n=7), aim of the app (not part of a health promotion strategy n=4, only monitoring for research purpose n=11), topics addressed in the app (n=2), and a combination of these exclusion criteria (n=9). Furthermore, studies were excluded if the primary component of the intervention did not involve a mobile app or the mobile app was not developed by the researchers (n=8). Eventually 15 studies were included. Information of the included studies was extracted into a structured summary table. This table was not ordered by study, but by the apps, because this is the focus of this review. Some studies described several apps and some apps were described in several studies. Information of interest was information about the target group, study design, health topic, aim of the app, working mechanism of the app, mode of delivery, and use of theories and behavior change techniques (Tables 1 -3).

The taxonomy developed by Abraham and Michie [16] was applied to determine the use of behavior change techniques in the apps. Data were extracted from the app description in the studies by two researchers (DD and WB). Subsequently, these findings were discussed and are described in Table 3. For example, we decided to assign behavior change technique 12, "prompt self-monitoring of behavior," when the app asked users to self-monitor their physical activity or daily intake. In all cases, this behavior technique appeared to be combined with behavior change technique 13, "provide feedback on performance," because—according to Abraham and Michie—this is already the case when the app provides summaries about reported behavior. We considered it to be relevant to distinguish between providing summaries only and providing evaluative feedback concerning the reported behavior and whether this is in line with goals or guidelines or not; for example, the recommended amounts of fruit and vegetable intake per day. This distinction is indicated in Table 3. Also with respect to technique 10, "prompt specific goal setting," we made a distinction and specified whether this concerned individual goal setting or whether goal setting was predefined and based on relevant public health guidelines. If an online buddy was part of the design of the app, then we allocated behavior change technique 20, "plan social support or social change."

Results

Mobile App Characteristics

The 15 included studies describe 12 apps in total (Table 1). All studies were published since 2010 and Western research institutes developed the apps; 7 studies had been conducted in the United States, 4 in Australia, 2 in the United Kingdom, and 2 in Germany.

Two apps strove for increased physical activity levels by making the users aware of their daily amount of physical activity and by encouraging users to exercise. Eight apps aimed for dietary improvements, and 2 apps targeted both topics. Regarding dietary improvements, the apps focused on increased fruit and vegetable intake, reduced consumption of sugar-sweetened drinks, reduced excessive intake of fast food, monitoring all foods and beverages consumed, and defining problem foods.

Table 1 presents the reach and duration of usage of apps. Reach represents the number of users of apps. Some apps focused especially on participants at high risk of becoming overweight or obese (ePASS, eVIP, eSIYP, eTIYP) or participants who are overweight (W8Loss2Go, MoSeBo/DiaTrace). Four apps focused specifically on users aged 11-18 years (Ak-Shen, FRapp, App-Hongu, MoSeBo/DiaTrace) and some studies also included participants older than 25 years (MMM, ePASS, eVIP, eSIYP, eTIYP). The duration of app usage varied from 1 lunch and meal (CHAT) to 6 months (MMM).

Ten apps function as monitoring tools for assessing dietary intake or physical activity levels (Table 2). Assessing dietary intake is either done by an app that analyzes pictures taken before and after food and beverages are consumed by users (CHAT, MoSeBo/DiaTrace, Recaller, FRapp) or by self-monitoring what users have eaten (eVIP, eSIYP, eTIYP, MMM). In terms of physical activity, users can specify the type and intensity of the activity (ePASS, App-Hongu) or the apps measure the physical activity levels with a built-in sensor, such as a pedometer or accelerometer (MoSeBo/DiaTrace).

Two apps have a different approach. The Ak-Shen app uses a Web-based platform that challenges users to execute activities and to share this information with others. Users can upload this information with Global Positioning System (GPS) and camera features that are included in the app. W8Loss2Go focuses on compulsive overeating by allowing users to list and photograph their problem foods and to set targets in order to tackle this problem.

Regarding the broader context surrounding the apps, most apps are applied as part of a prevention program. The apps ePASS, eVIP, eSIYP, and eTIYP are part of TXT2BFiT, a healthy lifestyle program, which consists of a booklet, a Web site, community blogs, text messages, emails, and the apps to monitor several health conditions. The CHAT app is also part of a broader program in which students are supported by text messages. MoSeBo/DiaTrace is integrated in a structured treatment and teaching program (STTP). The app is used to assess physical activity levels and eating habits. W8Loss2Go can be used as part of a therapeutic program for obese children. Ak-Shen is implemented at school as part of a physical education class. App-Hongu contributes to a broader intervention strategy that promotes walking via a Web site containing a social element; that is, youth register as teams that can compete with each other. Other apps function on their own (MMM) or the broader context is not clearly described (Recaller, Frapp).

Table 1. Characteristics of mobile apps.

No.	Mobile app	Topic (nutrition, physical activity): aim of the app	Described in the following study/studies (first author, year, country)	Reach (participants' characteristics)	Duration of the usage
1	ePASS	Physical activity: increase physical activity level.	Hebden, 2012, Australia [17]	21 participants at high risk of becoming overweight or obese, 18-35 years old (10 of them evaluated the app).	Not described
			Hebden, 2013, Australia [18]	RCT[a]has not yet been performed, unknown.	RCT has not yet been performed, unknown
2	eVIP	Nutrition: increase fruit and vegetable intake.	Hebden, 2012, Australia [17]	21 participants at high risk of becoming overweight or obese, 18-35 years old (10 of them evaluated the app).	Not described
			Hebden, 2013, Australia [18]	RCT has not yet been performed, unknown.	RCT has not yet been performed, unknown
3	eSIYP	Nutrition: reduce consumption of sugar-sweetened drinks.	Hebden, 2012, Australia [17]	21 participants at high risk of becoming overweight or obese, 18-35 years old (10 of them evaluated the app).	Not described
			Hebden, 2013, Australia [18]	RCT has not yet been performed, unknown.	RCT has not yet been performed, unknown
4	eTIYP	Nutrition: reduce excessive intake of high-fat takeout (fast-food) meals.	Hebden, 2012, Australia [17]	21 participants at high risk of becoming overweight or obese, 18-35 years old (10 of them evaluated the app).	Not described
			Hebden, 2013, Australia [18]	RCT has not yet been performed, unknown.	RCT has not yet been performed, unknown
5	CHAT (Technology Assisted Dietary Assessment (TADA) Project)	Nutrition: increase fruit and vegetable intake, reduce junk food intake.	Kerr, 2012, Australia [19]	RCT has not yet been performed, unknown. Intention is to include users aged 18-30 years living in the suburbs of Perth, Western Australia.	RCT has not yet been performed, unknown
			Zhu, 2010, USA [20]	78 participants (26 males, 52 females), 11-18 years old.	Not described
			Six, 2010, USA [21]	Sample 1: 78 participants (26 males, 52 females), 11-18 years old.	Sample 1: one lunch and meal
				Sample 2: 15 participants, 11-18 years old.	Sample 2: 1 day
			Six, 2011, Australia [22]	15 participants (12 boys, 3 girls), adolescents.	1 day
6	MoSeBo/DiaTrace	Nutrition, physical activity: weight reduction or stabilization.	Schiel, 2012, Germany [23]	124 participants (44% males, 56% females), average age 13.5 years.	On average 36.5 days
			Schiel, 2010, Germany [24]	30 overweight/obese participants, average age 14 years.	On average 4 days
7	Ak-Shen app (part of i-Challenge! program)	Nutrition, physical activity: increase physical activity, fruit and vegetable consumption, nutrition knowledge, motivation.	Mosqueda, 2012, USA [25]	30 healthy participants (21 males, 9 females), 11-14 years old.	8 weeks
8	MMM (My Meal Mate)	Nutrition: weight loss by self-monitoring of food and drink intake.	Carter, 2012, UK [26]	50 participants (students and staff).	7 days
			Carter, 2013, UK [27]	43 participants, 18-65 years old (66% males, 33% females).	6 months
9	Recaller[b]	Nutrition: raising awareness of dietary intake and eating pattern.	Suzuki, 2012, USA [28]	41 participants, college students (median age 22 years).	6 days
10	W8Loss2Go[c]	Nutrition: weight loss by identifying problem foods.	Pretlow, 2012, USA [29]	12 obese participants, 8-21 years old.	2 months

No.	Mobile app	Topic (nutrition, physical activity): aim of the app	Described in the following study/studies (first author, year, country)	Reach (participants' characteristics)	Duration of the usage
11	FRapp[c]	Nutrition: monitor dietary intake.	Casperson, 2013, USA [30]	17 participants, 11-14 years old.	3-7 days
12	App-Hongu[b]	Physical activity: encouraging reporting of miles walked in a physical activity program.	Hongu, 2013, USA [31]	30 participants, 11-14 years old.	Not described

[a]RCT: randomized controlled trial.

[b]Only a conference abstract was found and the authors did not respond to attempts to contact them.

[c]Only a conference abstract was found; studies are not yet published.

Table 2. Detailed information about mobile apps.

No.	Mobile app	Context	Short description of mobile app
1	ePASS	ePASS is part of the TXT2BFiT program, which consists of a booklet, a Web site, weight tracker, handouts, community blog, text messages, emails, personal coaching calls.	ePASS uses the target of moderate-level exercise for 30 minutes per day. Users can specify the type of activity and intensity and self-monitor their daily level of physical activity.
2	eVIP	eVIP is part of the TXT2BFiT program, which consists of a booklet, a Web site, weight tracker, handouts, community blog, text messages, emails, personal coaching calls.	eVIP allows users to monitor their daily intake of fruits and vegetables. A graphical display shows the number of fruits and vegetables the user recorded. As a reference, the app uses the targets of 2 servings of fruits and 5 servings of vegetables daily.
3	eSIYP	eSIYP is part of TXT2BFiT program, which consists of a booklet, a Web site, weight tracker, handouts, community blog, text messages, emails, personal coaching calls.	eSIYP allows users to specify the drink category (eg, water, tea or coffee, alcohol). The app presents users with a colored display with the total amounts of energy, sugar, and alcohol intake. The colors green, orange, and red indicate “ideal”, “acceptable”, and “too much” as threshold levels of intake, respectively.
4	eTIYP	eTIYP is part of the TXT2BFiT program, which consists of a booklet, a Web site, weight tracker, handouts, community blog, text messages, emails, personal coaching calls.	eTIYP allows users to specify the food and beverages consumed. A colored display shows the average energy and fat content of takeout meals, in which green indicates acceptable intake and red indicates excessive intake.
5	CHAT	CHAT used text messages to send users tailored feedback. Users are trained in using the app in advance and the app is currently developed to be used on an iPod touch.	CHAT provides users the ability to assess dietary intake (fruits, vegetables, junk food) by taking before and after pictures. Based on nutrition characteristics and volume estimation, tailored feedback and dietary recommendations are given regarding the estimated energy and nutrition.
6	MoSeBo/DiaTrace	The app is integrated in a structured treatment and teaching program (STTP) for overweight children and adolescents. The STTP consists of 28 therapeutic sessions in which personal goals are defined for each patient with respect to energy intake and physical activity.	The app consists of a built-in sensor that measures physical activity (mobile motion sensor, MoSeBo). The sensor measures the type, intensity, and duration of physical activity. The amount of physical activity is displayed on the display of the phone. With the camera (DiaTrace) eating habits are documented.
7	Ak-Shen app	i-Challenge! is an 8-week intervention that consists of an app and Web site and is part of a physical education class at junior high school. In a newsletter, a weekly i-Challenge! is delivered. An i-Challenge! is a small, fun, and challenging activity related to nutrition and physical activity intended to keep participants engaged in the project.	Ak-Shen app allows users to share activities with others. It consists of 3 components: 2 GPS-based mobile phone apps (GeoKnect and GeoSnap) and a social network, i-Challenge!. With GeoKnect and GeoSnap, the user can directly show on i-Challenge! what activity they do. With GeoKnect, a GPS-based feature, users can mark and describe points, lines, and areas of interest on a map. GeoSnap is a camera that captures photos and their descriptions and sends them automatically to the i-Challenge! Website.
98	MMM (My Meal Mate)	Users are also supported by tailored weekly text messages.	The MMM app allows users to set a weight loss goal and self-monitor daily calorie intake. Users select food and drinks consumed from a database and record items in an electronic food diary. Users can take photographs of their meals that serve as a memory aid. Physical activity can also be recorded in the diary.
9	Recaller	Not described.	Recaller is a nutrition assessment tool that allows users to take photos of all food eaten to improve diet awareness.
10	W8Loss2Go	Not described.	The app allows users to list and photograph their problem foods, with sequential withdrawal from each food. Furthermore, it includes a buddy and online community support.
11	FRapp	Not described.	FRapp is a food record app. It allows users to monitor dietary intake by taking before and after pictures of all foods and beverages consumed.
12	App-Hongu	The app is added to an 8-week online walking program that uses a Web site.	The app allows youth to report their walking miles.

Theoretical Basis

Of the 12 apps, 5 described behavioral theories that served as a foundation for the apps (Table 3). The 4 apps of the TXT2BFiT program (apps 1-4) are based on the transtheoretical model, also called stages of change [15,17]. Hebden et al [17] describe the modeling process outlined in this model called self-reevaluation and may be of particular importance to progress from the contemplation to the action phase. Their apps use images of good examples, such as young adults looking healthy who are drinking water or riding a bike. Presenting role models who perform the target behaviors can motivate users to change their behavior. Another example of using the model by Hebden et al [17] is that users receive motivational tips as a source of positive encouragement to enhance self-efficacy.

CHAT (app 5) is based on the self-determination theory (SDT), combined with motivational interviewing [19]. The SDT states the importance of intrinsic motivation in order to change a person's behavior [19]. Critical aspects are autonomy, feeling competent to perform the behavior, and whether the person feels appreciated and understood by others [32]. In CHAT the SDT is combined with motivational interviewing because the tone and content of messages is supposed to be more effective in supporting autonomous decision making, as opposed to giving "traditional advices." The app provides users the possibility to refuse information when not appreciated and sends tailored messages only. For example, a woman who does not drink alcohol does not receive any messages on alcohol consumption.

A behavior change theory, it is not specified which one, is applied in the development of the Ak-Shen app (app 7) [25]. This app is reported to focus on raising awareness and increasing motivation and provides tailored feedback to the users. Finally, the W8Loss2Go app (app 10) is not precisely based on a classic theory of changing behavior, but still the authors clearly underpin the theoretical base. They describe that the app focuses on problem foods and that coping skills are enhanced by showing other ways to handle negative emotions and neutralize cravings [29].

Subsequently, it was determined which behavior change techniques, identified by Abraham and Michie [16], were applied in the apps (Table 3). In a few studies, these techniques were clearly described, whereas in others they have been distilled out of the app descriptions given in the studies, as indicated in Table 3. The techniques "prompt self-monitoring of behavior" (technique 12) and "provision of feedback on performance" (technique 13) are most often applied, in 10 apps.

Another frequently applied technique is "specific goal setting" (technique 10), which is applied in 6 apps, mostly with general guidelines as being the reference for the target behavior (apps 1-4). As underpinned by several authors, it is important to provide contingent rewards (technique 14). These apps provide motivational tips (apps 1-4) or tailored messages (apps 5 and 8) based on the targeted behavior. The aim of these messages is to increase users' self-efficacy and to reinforce positive behavioral beliefs. Because the authors stress the importance of providing tailored feedback, possibly this technique is also applied in the Ak-Shen app (app 7).

Two apps primarily used other techniques than self-monitoring. The Ak-Shen app (app 7) provides adolescents with specific physical activity challenges (ie, treasure hunt, mapping, earth drawing, and tag) supported by the app, which incorporates a Global Positioning System. Furthermore, this app applies a technique involving social comparison. Users can share their activities with other members.

W8Loss2Go (app 10) allows users to list and photograph their problem foods in order to prompt barrier identification. The app aims at relapse prevention by providing coping skills, showing other ways to handle negative emotions and neutralize cravings. In line with Ak-Shen (app 7), this app uses a technique involving social support. Users are, for example, linked to a buddy. Furthermore, the MoSeBo app (app 6) virtually connects users with a buddy and provides the buddy information on performance, enhancing social comparison.

Table 3. Applied behavior change techniques in mobile apps.

No.	Mobile app	Theoretical basis	Behavior change techniques by Abraham and Michie [16] (In brackets is the number of the technique as numbered in the taxonomy, 2008).	Examples of applied behavior change techniques
1	ePASS	Transtheoretical model	Model or demonstrate behavior (9) Prompt specific goal setting (10) Prompt self-monitoring of behavior (12) Provide feedback on performance (13) Provide contingent rewards (14)	9: ePASS uses healthy role models. 10: ePASS shows the participants the recommended amount of daily physical activity (based on guidelines). 12: ePASS allows users to monitor their daily physical activity levels. 13: ePASS shows users the recorded amount of physical activity. 14: ePASS provides motivational tips.
2	eVIP	Transtheoretical model	Model or demonstrate behavior (9) Prompt specific goal setting (10) Prompt self-monitoring of behavior (12) Provide feedback on performance (13) Provide contingent rewards (14)	9: eVIP uses healthy role models. 10: eVIP shows the participants the recommended fruit and vegetable intake (based on guidelines). 12: eVIP allows users to monitor their fruit and vegetable intake. 13: eVIP provides (evaluative) feedback on the reported behavior. 14: eVIP provides motivational tips.
3	eSIYP	Transtheoretical model	Model or demonstrate behavior (9) Prompt specific goal setting (10) Prompt self-monitoring of behavior (12) Provide feedback on performance (13) Provide contingent rewards (14)	9: eSIYP uses healthy role models. 10: eSIYP shows the participants the allowed amount of sugar-sweetened drink intake. 12: eSIYP allows users to monitor their energy, sugar, and alcohol intake. 13: eSIYP shows users the recorded amount of energy, sugar, and alcohol intake (and values these amounts). 14: eSIYP provides motivational tips.
4	eTIYP	Transtheoretical model	Model or demonstrate behavior (9) Prompt specific goal setting (10) Prompt self-monitoring of behavior (12) Provide feedback on performance (13) Provide contingent rewards (14)	9: eTIYP uses healthy role models. 10: eTIYP shows the participants the allowed amount of take-out meals intake (based on guidelines). 12: eTIYP allows users to monitor their take-out meals intake. 13: eTIYP provides (evaluative) feedback on the reported behavior. 14: eTIYP provides motivational tips.
5	CHAT	Self-determination theory Motivational interviewing	Prompt specific goal setting (10) Prompt self-monitoring of behavior (12) Provide feedback on performance (13) Provide contingent rewards (14) Motivational interviewing (25)	10: CHAT sets goals based on dietary assessment. 12: CHAT allows self-assessment of dietary intake. 13: CHAT provides feedback on recorded nutrition performed (based on guidelines). 14: The participants receive messages to increase motivation. 25: Tone and content is carefully designed to enhance autonomous decision making and users can refuse to receive messages on particular content.
6	MoSeBo/DiaTrace	Not described	Prompt self-monitoring of behavior (12) Provide feedback on performance (13) Plan social support or social change (20)	12: MoSeBo/DiaTrace measures physical activity. 13: MoSeBo/DiaTrace displays the performed amount of physical activity. 20: Participants are virtually connected with a “buddy”. The current results of the buddy are shown on the app.

No.	Mobile app	Theoretical basis	Behavior change techniques by Abraham and Michie [16] (In brackets is the number of the technique as numbered in the taxonomy, 2008).	Examples of applied behavior change techniques
7	Ak-Shen app	Behavior change theory; not specified by the authors[a]	Set graded tasks (7) Provide instruction (8) Provide opportunities for social comparison (19)	7: The participants received four different challenges on their phones. 8: Information about the physical activities is delivered via the i-Challenge! social network. 19: The i-Challenge! social network is a virtual community that allows participants to upload their activities and share it with other members.
8	MMM (My Meal Mate)	Authors stress the importance of goal setting, self-monitoring, and feedback messages	Prompt specific goal setting (10) Prompt self-monitoring of behavior (12) Provide feedback on performance (13) Provide contingent rewards (14)	10: The app allows users to set weight loss goals. 12: Participants are asked to self-monitor their dietary intake. 13: The app displays daily calorie intake. 14: Feedback via tailored text messages weekly.
9	Recaller	Not described	Prompt self-monitoring of behavior (12) Provide feedback on performance (13)	12: The app provides the ability to monitor dietary intake. 13: The app provides feedback on dietary intake, based on photos that users take.
10	W8Loss2Go	Identification of problem foods and enhancing coping skills	Prompt barrier identification (5) Plan social support or social change (20) Relapse prevention (23)	5: The user is able to list and photograph his/her problem foods. 20: The app includes a buddy and online community support. 23: Relapse prevention is provided by determining problem food, increasing self-esteem, and coping skills augmentation.
11	FRapp	Not described	Prompt self-monitoring of behavior (12) Provide feedback on performance (13)	12: The app provides the ability to monitor dietary intake. 13: The app provides feedback on dietary intake.
12	App-Hongu	Not described	Prompt self-monitoring of behavior (12) Provide feedback on performance (13)	12: The participants registered the miles walked with their mobile phones. 13: The app directly shows the results on a Web site.

[a]The authors indicate that the app raises awareness, increases motivation, and provides tailored feedback.

Lessons Learned

To make statements regarding the lessons learned, it is important to know which research methods were used to test the apps. Only 2 studies measured the effect of using the app on the target group: Schiel et al [23] and Mosqueda [25]. Hebden et al, 2013 [18] and Kerr, 2012 [19] described a protocol for a randomized controlled trial (RCT), for assessing the impact in the future. At this moment, lessons learned are known only from pretesting the app among the target population, as is the case for the other studies (see Table 1 , column “Reach,” for a description of the target population).

Schiel et al [23] (MoSeBo) reported a significant weight reduction among users of the app but made no comparison to a control group. Furthermore, these participants participated in an STTP and the precise contribution of the app has not been specifically investigated. The researchers stated that the app was successful at improving the intrinsic and extrinsic motivation of the participants.

Mosqueda [25] (Ak-Shen) performed a nonrandomized experiment suggesting the potential of a smartphone-based intervention. No significant changes were found between the app group and control group, but baseline characteristics differed, such as age, height, weight, and ethnicity, and the sample size was small (30 adolescents).

In several studies, the pretests indicated that the users were willing and able to use the app. The users of CHAT (app 5) aged 11-18 years considered the software easy to use, and no difference in proficiency with the tool was found between users aged 11-14 years and 14-18 years [21]. The Recaller (app 9) was extremely easy or easy to use, according to participants [28]. Hongu et al [31] (app 12) stated that the “mobile phone group” had a higher response rate compared with the “website group,” suggesting a useful contribution of the app. Pretlow and Gearhardt [29] (W8Loss2Go) stated that the app was understandable to all participants, except for those under age 10 years. This would mean that we found no evidence that apps may be feasible for users under the age of 10 years, because their study included children aged 8-9 years.

Five of the included apps (apps 1-4 and app 8; described in 2 studies) also specified users outside the age range as their target population, that is, people older than 25 years. According to apps 1-4, qualitative feedback provided by young adults related

to practical features such as the speed of using the app and the necessity of a login, which was considered a barrier.

Duration of usage varies largely among the apps, which makes it difficult to make statements regarding feasibility of long-term use. Some apps were only tested for several days: CHAT (app 5) was used for 1 day, Recaller (app 9) for 6 days, and FRapp (app 11) for 3-7 days [21,28,30]. Other apps were used for a longer period: the MoSeBo/DiaTrace (app 6) on average for 36.5 days, the Ak-Shen app (app 7) for 8 weeks, MMM (app 8) for 6 months, and W8Loss2Go (app 10) for 2 months [23,25,28,29].

Discussion

Key Findings

Limited research has been done so far on mobile apps and their use in health promotion for adolescents and students. This review found only 15 studies that describe the use of 12 apps to improve the health of adolescents and students regarding their dietary intake and physical activity levels. This may seem surprising because apps are widely used, especially among adolescents and students; 23% of the European adolescents download free apps on a daily basis [33]. Furthermore, in recent years many apps have been developed. Breton et al [34] found 204 apps for weight control on iTunes on September 25, 2009, and Conroy et al [4] found 167 top-ranked apps for physical activity in 2013. However, according to an appropriate description of apps in scientific literature, the number is very disappointing, and obviously, this limits the possibilities for an in-depth discussion of the advantages and disadvantages of using certain theories or techniques of changing behavior in apps.

The limited number of publications concerning apps indicates the difficulty of capturing technology in science. Because of the dynamic and rapid development of apps and the long processes of doing research and publishing, it is difficult to provide up-to-date information. The MoSeBo/DiaTrace app by Schiel et al [23] serves as an example. Although they published about 2 years ago, the mobile phone they used seems to be outdated (based on author's evaluation of the absence of a touchscreen). It should be recognized that it is therefore more difficult to make statements corresponding to the current situation of app development.

For 5 of the 12 included apps, the behavioral theory underpinning their development was clearly specified. The 4 apps developed by Hebden et al [17,18] used the transtheoretical model, which is also called stages of change [15,17]. The apps use role models who perform the target behavior, which can motivate users to change their behavior. CHAT is based on the SDT and supports autonomous decision making by the users. It is of interest that one of the included apps in our review that did not primarily focus on self-monitoring, that is, the W8Loss2Go app, has a theoretical base in addiction-derived theories. W8Loss2Go targets compulsive overeating, which is considered as addictive behavior, by barrier identification, offering social support, and relapse prevention. The authors did not specify the used theory in detail. More research should be carried out in this area, because the available evidence is sparse.

We applied the taxonomy of behavior change techniques [16] to the identified apps for this review. It became clear that healthy diets and physical activity are mainly promoted by means of self-assessment tools. Out of 12 apps, 10 were designed either to monitor nutrition intake or to monitor duration or the intensity of physical activities. These apps applied behavior change techniques such as prompting self-monitoring and providing feedback on performance. By facilitating self-monitoring and providing feedback on performance, apps can increase awareness about the dietary intake and physical activity levels of the users. This suggests that apps can be suitable as a monitoring tool, which is underpinned by Breton et al [34] who found that of 204 apps included in their review, 43% provided a food diary tool.

Besides the behavior change techniques of self-monitoring and providing feedback on performance, specific goal setting combined with personal feedback messages is also considered as a promising approach. Kohl et al [11] also concluded that these approaches, goal setting and personal feedback, are effective elements in Web-delivered interventions. High-quality evidence supporting effectiveness of these apps, however, is not yet available. A pilot randomized trial of Carter et al [27] found significant weight reduction among the app users. Although the app is included in this review because the target population involves students, the RCT participants consisted of adults, most of them older than 25 years. This result may also apply to students, and because we found no strong arguments counteracting this, for example, from the process evaluation, we consider this a promising result. Besides the significant weight reduction, trial retention and adherence were also significantly higher in the smartphone group compared with the other groups. These results indicate the potential of applying these behavior change techniques in apps to improve the health of adolescents and students; however, no conclusions can be drawn regarding the effectiveness of these apps.

Three apps (MoSeBo/DiaTrace, Ak-Shen, and W8Loss2Go) offer a social function and can be categorized as social media. An example is the Ak-Shen app that uses an online platform that challenges users to execute activities and to share this information with others. The app contributes to users' motivation by providing rewards and opportunities for social comparison. Kaplan and Haenlein [35] describe that research into social media should acknowledge features like social presence and media richness, and social processes, which includes self-presentation and self-disclosure. As there is a clear gap in literature, it would be valuable to conduct more research into social features in mobile apps and their effectiveness in health promotion for adolescents and students. Several apps provided social comparison opportunities or a buddy system, but the behavior change technique “provide information on others' approval” did not appear to be specifically applied.

It should be clarified that we described techniques (summarized in Table 3) that were applied in the apps only, although almost all the included apps were or can be implemented as part of a broader intervention strategy. It probably explains why behavior

change techniques, like providing information on the link between behavior and health or providing general encouragement, were not clearly present in the app descriptions. These techniques are probably applied within the broader intervention strategy, strengthening the potential effect of the app. This is in line with Crutzen et al [10] who stated that apps are more effective when they are embedded in existing structures, such as health care and schools.

According to the technique "teach about environmental cues" (15), we identified one app demonstrating this potential [36]. However, this app was not included in this review because it is used primarily for research purposes (monitoring), instead of changing behavior. Regarding apps for adolescent, gaps in literature seem to be in using techniques such as "(follow-up) prompts of practice" (18) or "review of goals" (11). More research is recommended on the application of behavior change techniques among adolescents and students.

Mobile apps have the potential to tackle health issues. Several arguments are mentioned in the studies. Hebden et al [17] stated that the features of apps—widespread and increasing use, dynamic technologies, and use of existing features like Internet, cameras, and GPS—make them potentially able to improve health. Apps are easy to use and to access [17,34]. Carter et al [27] have underpinned the advantages as compared with traditional methods ("paper diaries"). Obviously, by linking apps to databases, and subsequently providing feedback on energy intake (calories) or energy expenditure based on self-monitoring, useful feedback is possible in an efficient way, which enhances awareness and goes beyond the registration of food intake only.

Our review not only supports the idea that apps can be a promising tool as part of health promotion strategies but also highlights that the scientific base for adolescents is small. Hardly any evidence on their effectiveness is available from high-quality research studies. Even less evidence is available for longer-term usage, which is supposed to enhance maintenance of any changes in behavior that may be achieved when using the app. Most apps are tested on a small scale only and for a short period. It is unclear for what duration the users are willing to test the apps. The MMM app (app 8) was used for 6 months (which is the longest period), but within the context of an RCT mainly involving adults [27]. The average number of adherence days was 92 in the smartphone group, as compared with 35 days and 29 days in the other two groups [27]. Furthermore, only 5 out of 12 apps described a theoretical basis for the app, and several promising techniques had either not yet been applied or only been applied in a few apps. Finally, it is of particular interest to study whether a social aspect contributes to the effectiveness of mobile apps. In general, the importance of social media for young people, for example, regarding self-presentation, self-disclosure in social processes, shaping their identity, and so on, seems to be worth exploring more for health promotion strategies.

Strengths and Limitations

The strength of this review is that it approaches a new area of research in which there is still much to discover and to learn. Although the search revealed a large number of hits, as summarized in appendix 3 , only a limited number of studies met the inclusion criteria. Only two studies investigated the effect of using the apps, so it was impossible to perform a systematic review and meta-analysis on effectiveness. However, the studies did provide interesting information that could be used when designing a new mobile app. Five studies had not yet been published in a peer-reviewed journal, and information about the app was derived from an abstract [28-31] and provided by the authors [25]. Hence, this review provides an overview of the current scientific "state of the art" in this rapidly developing field and presents some upcoming studies.

Overall, it is useful to have used the taxonomy of techniques for this review, because it clearly demonstrates the focus of these apps. It should be noted, however, that this taxonomy is primarily proposed for health promotion in adults. Some techniques, which may be particularly important for young people, could not clearly be coded; for example, the incorporation of a game or competition element. This was not part of the Hongu-app itself [31], but it was part of the broader intervention strategy, since the winning teams received a reward. With respect to the technique "demonstrate behavior by expert" (technique 9), not necessarily experts but also peers may be of relevance to youth; we coded several apps, using peers, by applying this technique (see Table 3).

Furthermore, inaccuracies may have occurred by applying the taxonomy of behavior change techniques [16] because of several reasons. Some of the apps were poorly described, and in a few situations, the same mobile app was described in more than one study. In that case, adjustments were made over time, possibly, but these were not always clearly described. An explanation for the large variation in description of the apps is the difference in research focus. Several studies were protocols for RCTs, others described the development of the app, and in some, entire intervention programs were described. Together with the rapid development of mobile apps, as described in the beginning of this discussion, it is questionable whether a review or traditional research methodology in general is the most appropriate method to gather information concerning mobile apps. Research with a qualitative methodology, capturing context and changing developments not only regarding technological developments but also regarding rapidly changing trends and hypes among young people, may be suitable as well.

Many different terms are used to describe mobile apps: smartphone applications/smart phone applications, mobile phone-based healthy lifestyle program, using mobile devices/mobile phones, electronic health technology, and a mobile telephone record; this makes the search for relevant studies very difficult. It is because of this that the two searches in MEDLINE were not entirely consistent. As a result of a small adjustment in the research terms, not all studies found in search 1 were also included in search 2. Therefore, we decided to use both searches and to remove duplicates. It appeared necessary to use a broad definition for mobile apps. Some studies did not seem to describe a "real" mobile app. An example is the application of Schiel et al [23,24], which is implemented on an outdated mobile phone type that could be questioned as being a smartphone. However, after consideration, it was decided to include the app for this review because it met the other criteria

and it provided valuable information, including being an illustration of the apparent mismatch between fast developments in technological possibilities as compared to scientific research, which is a slower process.

Conclusions

The present review aimed to identify mobile apps to be used in health promotion for adolescents and students. It became clear that apps are suitable as monitoring tools for both dietary intake and physical activity. The apps enable users to set targets and self-monitor, provide tailored feedback, and subsequently raise awareness and increase motivation. These types of monitoring tools can function independently, but most of the identified apps are part of a treatment program or support educational methods, that is, methods used in schools. Three apps facilitated social interaction and support and can be characterized as social media. Subsequently, these "social" apps apply other behavior change techniques, such as providing opportunities for social comparison and social support, in comparison with monitoring apps. The limited number of studies clearly indicates the need for additional research, and one may question whether this should be performed in a "traditional" way. Further research is recommended on the effectiveness, reach, and long-term use of mobile apps and to identify other possibilities to tackle health issues with mobile apps, especially with respect to their potential social features.

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Conflicts of Interest

JB is a staff member of the WHO Regional Office for Europe. The authors alone are responsible for the views expressed in this publication and they do not necessarily represent the decisions or the stated policy of the WHO.

Multimedia Appendix 1

Search strategy Embase, MEDLINE, and PsycINFO, November 27, 2013.

[PDF File (Adobe PDF File), 85KB - mhealth_v4i2e39_app1.pdf]

Multimedia Appendix 2

Search strategy MEDLINE, November 14, 2013.

[PDF File (Adobe PDF File), 59KB - mhealth_v4i2e39_app2.pdf]

Multimedia Appendix 3

Eligible table.

[PDF File (Adobe PDF File), 123KB - mhealth_v4i2e39_app3.pdf]

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Abbreviations

GPS: Global Positioning System
RCT: randomized controlled trial
SDT: self-determination theory
STTP: structured treatment and teaching program

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Original Paper

Mobile Technology for Vegetable Consumption: A Randomized Controlled Pilot Study in Overweight Adults

Sarah Ann Mummah[1,2], MPhil; Maya Mathur[3], MS; Abby C King[1], PhD; Christopher D Gardner[1*], PhD; Stephen Sutton[2*], PhD

[1]Stanford Prevention Research Center, Stanford University School of Medicine, Stanford, CA, United States

[2]Cambridge Institute of Public Health, University of Cambridge School of Clinical Medicine, Cambridge, United Kingdom

[3]Quantitative Sciences Unit, Stanford University School of Medicine, Stanford, CA, United States

[*]these authors contributed equally

Corresponding Author:
Sarah Ann Mummah, MPhil
Stanford Prevention Research Center
Stanford University School of Medicine
1265 Welch Road
Stanford, CA 94305-5411
United States
Phone: 1 650 723 7822
Fax: 1 650 725 6247
Email: sm885@cam.ac.uk

Abstract

Background: Mobile apps present a potentially cost-effective tool for delivering behavior change interventions at scale, but no known studies have tested the efficacy of apps as a tool to specifically increase vegetable consumption among overweight adults.

Objective: The purpose of this pilot study was to assess the initial efficacy and user acceptability of a theory-driven mobile app to increase vegetable consumption.

Methods: A total of 17 overweight adults aged 42.0 (SD 7.3) years with a body mass index (BMI) of 32.0 (SD 3.5) kg/m^2 were randomized to the use of Vegethon (a fully automated theory-driven mobile app enabling self-monitoring of vegetable consumption, goal setting, feedback, and social comparison) or a wait-listed control condition. All participants were recruited from an ongoing 12-month weight loss trial (parent trial). Researchers who performed data analysis were blinded to condition assignment. The primary outcome measure was daily vegetable consumption, assessed using an adapted version of the validated Harvard Food Frequency Questionnaire administered at baseline and 12 weeks after randomization. An analysis of covariance was used to assess differences in 12-week vegetable consumption between intervention and control conditions, controlling for baseline. App usability and satisfaction were measured via a 21-item post-intervention questionnaire.

Results: Using intention-to-treat analyses, all enrolled participants (intervention: 8; control: 9) were analyzed. Of the 8 participants randomized to the intervention, 5 downloaded the app and logged their vegetable consumption a mean of 0.7 (SD 0.9) times per day, 2 downloaded the app but did not use it, and 1 never downloaded it. Consumption of vegetables was significantly greater among the intervention versus control condition at the end of the 12-week pilot study (adjusted mean difference: 7.4 servings; 95% CI 1.4-13.5; *P*=.02). Among secondary outcomes defined a priori, there was significantly greater consumption of green leafy vegetables, cruciferous vegetables, and dark yellow vegetables (adjusted mean difference: 2.6, 1.6, and 0.8 servings; 95% CI 0.1-5.0, 0.1-3.2, and 0.3-1.4; *P*=.04, *P*=.04, and *P*=.004, respectively). Participants reported positive experiences with the app, including strong agreement with the statements “I have found Vegethon easy to use” and “I would recommend Vegethon to a friend” (mean 4.6 (SD 0.6) and 4.2 (SD 0.8), respectively, (on a 5-point scale).

Conclusions: Vegethon demonstrated initial efficacy and user acceptability. A mobile app intervention may be useful for increasing vegetable consumption among overweight adults. The small sample size prevented precise estimates of effect sizes. Given the improved health outcomes associated with increases in vegetable consumption, these findings indicate the need for larger, longer-term evaluations of Vegethon and similar technologies among overweight adults and other suitable target groups.

Trial Registration: ClinicalTrials.gov NCT01826591; https://clinicaltrials.gov/ct2/show/NCT01826591 (Archived by WebCite at http://www.webcitation.org/6hYDw2AOB)

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KEYWORDS

health behavior; cell phones; telemedicine; eating; diet; vegetables; randomized controlled trial; pilot projects

Introduction

Inadequate consumption of vegetables and fruits is responsible for up to 2.6 million deaths worldwide, according to a 2003 estimate by the World Health Organization [1]. Greater consumption of vegetables and fruits is associated with reduced risks of cardiovascular disease, stroke, cancer, and all-cause mortality [1-8]. It has been suggested that these protective effects are greater for vegetables than for fruits [8] and follow a dose-response relationship [6,8,9] with benefits seen in up to 7+ servings daily [8]. Vegetables in particular are rich in phytochemicals, including vitamins and trace minerals, that may protect cells against carcinogenesis [10,11]. They are also high in water and fiber and can promote weight loss and weight management by reducing energy density, promoting satiety, and decreasing energy intake [12,13]. In recognition of these many benefits, a national "5-a-day" campaign was launched in the United States in 1991 to encourage greater consumption of vegetables and fruits. However, Americans' consumption of vegetables significantly decreased during the subsequent decade [14], and despite current United States Department of Agriculture (USDA) recommendations to consume 5-6 servings of vegetables per day [12], US adults consume an average of just 1.7 (standard error (SE) 0.03) servings of vegetables (excluding fried potatoes) each day [14].

Behavioral interventions to increase vegetable and fruit consumption have led to modest increases in daily intake [15]. However, the typical face-to-face approaches used in behavioral interventions to achieve and sustain increased vegetable consumption often cannot be realistically implemented at the population level [15], particularly given the high cost of most current strategies [16] (eg, time demands, the need for trained staff, and so forth [17]). Mobile apps present an attractive alternative for delivering scalable dietary behavior change interventions for a number of reasons [18]. Rates of mobile phone adoption among US adults have increased dramatically during recent years, from 35% in 2011 to 56% in 2013 [19], making mobile phone-based interventions ripe for dissemination to whole populations. Individuals' tendencies to carry their phones with them everywhere means that such interventions can provide significantly more touch points, reaching individuals at nearly any time or place [20]. Additionally, the rapidly improving technical capabilities of mobile phones enable the potential for timely feedback, personalization, and interactivity to maximize the potential effectiveness of interventions over time [21].

An explosion of health-promoting mobile apps has occurred in recent years [22] including apps to promote weight control [23], healthier eating [24-26], and greater vegetable consumption [27]. However, most mobile health (mHealth) apps are yet to undergo evaluation in randomized trials or incorporate theory-based strategies known to drive changes in health behaviors [28-30]. Theory-driven behavior change techniques [31] may form the basis of apps that more effectively produce improvements in health behaviors. Investigators have called for both the theory-informed development and rigorous evaluation of mobile phone-based interventions [32,33]. With the mHealth field still in its infancy, it is likely that the most effective approaches are yet to be explored.

This pilot study (trial registration: ClinicalTrials.gov NCT01826591) aimed to assess the initial efficacy and user acceptability of Vegethon, a stand-alone mobile app designed to increase vegetable consumption through the creative application of behavior change theory and techniques. It is among the first apps specifically targeting only vegetable consumption to undergo evaluation in a randomized controlled study of adults attempting to lose weight.

Methods

Study Design

A randomized controlled study design was used, with a 1:1 allocation ratio of intervention to wait-listed control (12-week delay) participants. During a pre-randomization orientation session taking place face-to-face, participants were instructed that the mobile app was intended to support them in increasing their vegetable consumption and that it was ideally to be used for 1-2 minutes on a daily basis. They were instructed to avoid using any other apps focused on vegetable consumption for the duration of the study. Participants providing written consent were requested to complete a Web-based, self-administered baseline questionnaire. All participants who completed the questionnaire were randomized. Participants in the intervention condition were instructed to use the app for a minimum of 6 weeks. Outcome data were collected from both conditions using a Web-based questionnaire self-administered 12 weeks after randomization. To prevent contamination among conditions, the app was made available to intervention participants only through the distribution of single-use registration codes. The CONSORT-EHEALTH guidelines were followed in reporting this study (Multimedia Appendix 1).

Participants

Participants were overweight adults motivated to lose weight and eat healthier. Individuals were recruited from an ongoing 12-month weight loss trial (n=609) based at Stanford University (parent trial), in which participants were aged 18-50 years, had an initial body mass index (BMI) of 28-40 kg/m^2, were non-diabetic and non-hypertensive, had no cancer or heart, renal, or liver disease, and lived in the geographical area surrounding Stanford. The added eligibility criterion for this pilot study was ownership of an iPhone. All participants provided written informed consent, and this research was approved by the Stanford University Human Subjects Committee.

Parent Trial

The study was implemented during months 7-10 (ie, maintenance phase) of the parent trial. In the parent trial, participants were randomized to either a low-fat or a low-carbohydrate diet for 12 months and attended 22 evening classes led by a health educator. Both parent trial treatment groups were encouraged to include vegetables in their daily diets. Parent trial participants who chose to concurrently participate in this pilot study were re-randomized to receipt of the mobile app or a wait-listed control condition. Thus, any potential spillover effects of the parent trial on vegetable consumption affected both intervention and control conditions in this study.

Randomization

Participants were randomized and assigned prospectively via a balanced assignment approach designed to ensure balance across mobile intervention assignment and both elements of parent trial treatment assignment, consisting of (1) diet group (low-carbohydrate or low-fat) and (2) health educator (of 4 possible health educators). Because the randomized parent trial was underway at the time of this study, the diet group and health educator could not be manipulated and were instead treated as nested strata. Participants in this study were randomly assigned within these strata via a randomized, balanced block size of 4; subsequent participant assignments were selected via an a priori, deterministic procedure. This randomization assignment procedure was preferable to other randomization approaches because it ensured balance in all 3 variables at any given sample size of this pilot trial. Additionally, it was preferable over sequentially adjusted randomization procedures such as Efron's biased coin [34] because it allowed all assignments to be created prospectively.

Intervention

Participants randomized to the pilot study intervention condition completed a short Web-based tutorial that described the fully automated mobile app and its use. The tutorial guided them through the process of downloading the app onto their iPhones from the iTunes App Store on December 4, 2014, creating a user account with their individual registration code, and setting their initial goals for quantity and variety of vegetable consumption.

Vegethon [35] was a stand-alone mobile app that enabled self-monitoring of vegetable consumption and included a constellation of theory-driven features to maximize behavior change and sustain user engagement. Formative research indicated that this target population desired a simple and efficient means of self-monitoring. Self-monitoring is among the most widely used behavior change techniques in mobile apps to change health behavior [36]. It is acknowledged to be a critical component of behavior change interventions [37] and can be viewed as part of the process of self-regulating behavior [38]. Vegethon enabled swift vegetable logging by tapping on different vegetable icons (eg, eggplant, arugula) to indicate the number of servings of each vegetable consumed. To facilitate weight loss and weight maintenance in the context of the parent trial, the app focused on non-starchy vegetables with lower energy density and excluded starchy vegetables such as potatoes and corn. Tapping on each vegetable icon increased its quantity in increments of 1/2 servings. To reduce the cognitive load associated with self-monitoring, users were instructed by the app to estimate 1 vegetable serving as approximately the size of their fist. Users were able to select and modify goals for the quantity and variety of their daily vegetable consumption on 2 sliding scales ranging from 1 to 10 servings or types, each anchored by an “average” value of 2, “recommended” value of 5, and “superstar” value of 8. Default values [39] were set to the recommended 5 servings and 5 types of vegetables.

Overall, the intervention was grounded in behavioral theory, emphasizing the importance of centering an intervention around the *process* of behavior change (eg, the fun of tapping on colorful vegetable icons; the pride in surpassing a friend's vegetable score). This process motivation strategy stands in contrast to interventions focusing on the eventual outcomes of behavior change (eg, improved health) that can often be too far in the future to motivate and sustain behavior change [40]. Several theory-driven elements aiming to increase this type of process motivation complemented the primary self-monitoring component of Vegethon. To increase elements of fun and challenge, for example, 7 ongoing challenges were included that ranged from easy to difficult to perform (eg, *Breakfast Champ: Eat any vegetable before 11 am*). Similarly, elements of surprise and choice were incorporated through surprise challenges delivered to users via push notifications every 4 days, enabling the selection of a desired challenge. Competition, which has been shown by Lepper and colleagues [41] to increase intrinsic motivation for behavior change, was applied through a leaderboard in which users competed against “other Vegethoners” who were “most similar” to them. Finally, to foster a process of identity revision toward one who is a vegetable eater [42], each participant was referred to as a *Vegethoner* throughout the intervention.

As with most mHealth interventions, the intervention made use of opportunities for just-in-time feedback in a number of ways. Short-term progress monitoring was displayed with vertical bar graphs showing the current day's goals versus consumption. Long-term progress monitoring was displayed with horizontal bar graphs showing consumption for each of the previous 7 days and 7 weeks. Feedback on the fulfillment of goals and challenges was reinforced through in-app notifications. Just-in-time prompts to log vegetables were delivered most evenings at 9 pm through push notifications.

Blinding

Researchers who performed data analysis were blinded to condition assignment. Randomization was performed by a researcher who had no contact with participants and used a random, computer-generated allocation sequence to assign participants to each condition. Enrollment and post-randomization communication with participants were subsequently performed by a research assistant who did not play a role in the data analysis. All parent trial staff members, including the dietitians leading the health education classes, were blinded to condition assignment, and participants were

instructed not to discuss the app with their health educator or with other participants.

Data collection

App Usage

App usage was measured using inbuilt software tracking the date of app download, number of servings logged for each vegetable type, and time and date that logging occurred. Data were tracked for each participant using their individually assigned registration codes.

Vegetable Consumption

To assess the primary outcome of daily vegetable consumption at baseline and 12 weeks after randomization, an adapted version of the validated semiquantitative Harvard Food Frequency Questionnaire (FFQ) was used [43,44]. As with the Harvard FFQ, commonly used portion sizes for each vegetable (eg, 1 onion, 1/2 cup of broccoli) were specified, and participants were asked to indicate how often, on average, during the past week, they had consumed each type and amount of food. All 28 questions on vegetable consumption comprising 33 vegetables were included from the Harvard FFQ, and 8 response categories were possible, ranging from 0 to ≥6 times per day [45]. Daily vegetable intake was calculated for each participant following an established method [46,47] in which the daily frequency of consumption for each vegetable item was multiplied by the number of servings represented by the specified portion size, based on USDA guidelines [48], and subsequently combined to yield total daily vegetable servings. Vegetable subgroups were defined a priori based on established criteria [49] adapted for specific use with the Harvard FFQ [50,51]. Subgroups included green leafy vegetables (kale, mustard greens, chard, spinach, iceberg or head lettuce, romaine or leaf lettuce), cruciferous vegetables (broccoli, cauliflower, cabbage, coleslaw, brussels sprouts), dark yellow vegetables (carrots, carrot juice, yams, sweet potatoes, dark orange winter squash), tomatoes (tomatoes, tomato juice, V8 juice, tomato sauce, salsa, picante or taco sauce), beans/lentils (beans, lentils, tofu, soy burger or other soy protein), and other vegetables (eggplant, zucchini or other summer squash, celery, string beans, peas, lima beans, corn, mixed vegetables, stir-fry, vegetable soup, green or red peppers, onions). All vegetable subgroups apart from beans/lentils were assessed as secondary outcomes. Beans/lentils, which were not targeted by the intervention, were assessed as a control measure.

App Usability and Satisfaction

Usability of and satisfaction with the mobile app were assessed using a 21-item questionnaire, administered 12 weeks after randomization to the intervention condition only, and adapted from similar surveys used by King et al [52] to assess user acceptability of mHealth interventions. Participants were asked to rate their level of agreement or disagreement with each statement on a 5-point Likert-type scale.

Statistical Analysis

A convenience sample drawn from the parent trial was used for this pilot study. An analysis of covariance (ANCOVA) was used to assess differences between intervention and control conditions, with vegetable consumption as the dependent variable, condition assignment as the fixed factor, and baseline value of the dependent variable as a covariate. The use of ANCOVA was appropriate for a small sample size as it can be considered a special case of regression, in which a conservative rule of thumb is to have at least 10 subjects per predictor variable; in the present analysis with one predictor variable, a minimum total sample size of 10 was reasonable to satisfy parametric assumptions and minimize the chance of overfitting [53]. An intention-to-treat analysis was used such that baseline observations were carried forward when participants were lost to follow-up. A sensitivity analysis with multiple imputations to account for missing data was also used. Five imputed datasets were created using the chained equations method and pooled estimates using Barnard-Rubin adjusted degrees of freedom [54,55]. Descriptive statistics were used to analyze participant baseline characteristics and user acceptability of the mobile app. SPSS Statistics software version 22.0 (IBM, New York) was used.

Results

Participants

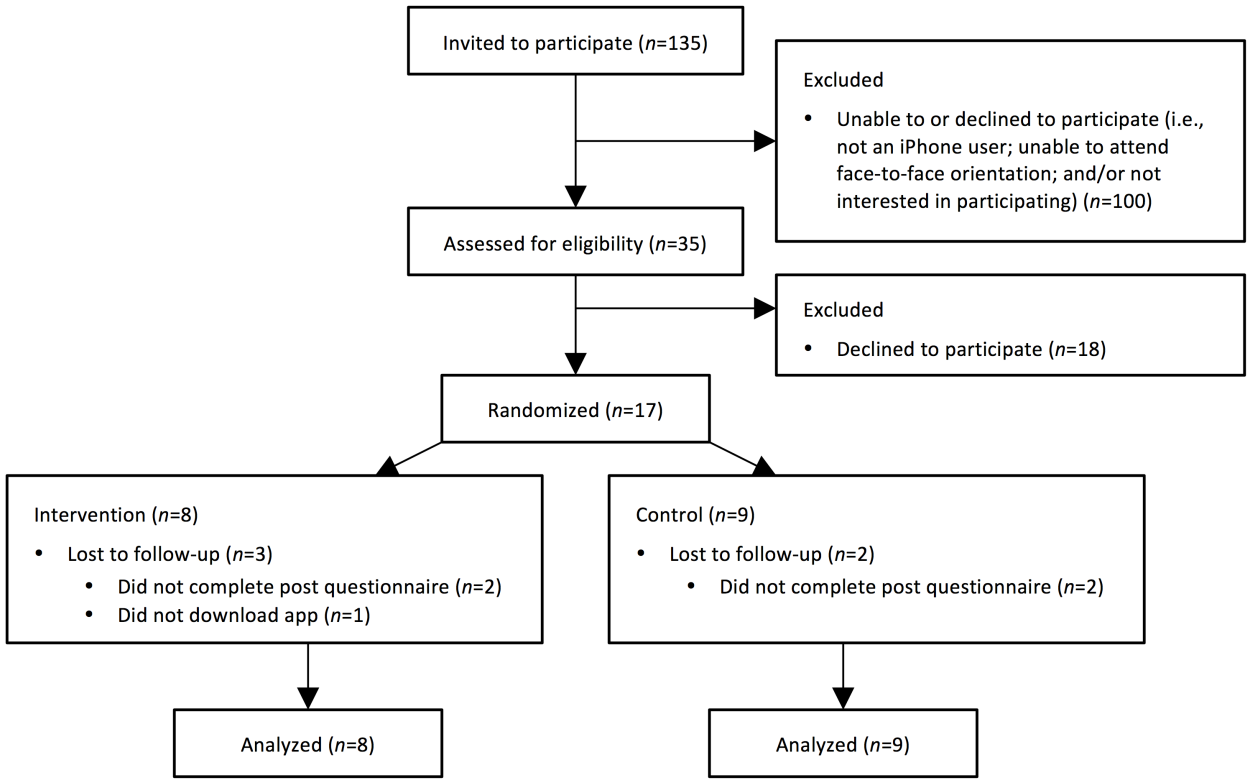
Participant study flow is presented in Figure 1. Enrollment began in October 2014, and the study ended in February 2015. A subset of participants (n=135) enrolled in the parent trial at a time point coinciding with this pilot study were invited to participate. Thirty-five participants responded to an email indicating that they (1) had an iPhone, (2) wished to participate in a mobile app substudy, and (3) were willing to attend a face-to-face orientation session. Among these 35 individuals, 17 completed a baseline questionnaire and were randomized and analyzed (intervention: 8; control: 9). Participant baseline characteristics are summarized in Table 1. Although there were more women than men in the control versus intervention conditions, the two conditions were comparable in age, BMI, and race and ethnicity. Randomization resulted in 2 conditions that were balanced across parent trial treatment assignment and parent trial health educator (Table 1).

Table 1. Participant baseline characteristics.

Characteristic	Control	Intervention
Gender, n (%)		
Female	7 (78)	4 (50)
Male	2 (22)	4 (50)
Age in years, mean (SD)	41.2 (7.6)	42.9 (7.3)
BMI[a] in kg/m^2, mean (SD)	31.7 (3.8)	32.3 (3.3)
Race/ethnicity, n		
White	7	6
Asian	1	0
Other	1	2
Parent trial treatment assignment, n		
Low-carbohydrate diet	5	4
Low-fat diet	4	4
Parent trial health educator assignment, n		
A	3	2
B	3	3
C	1	2
D	2	1

[a]BMI: body mass index.

Figure 1. CONSORT flowchart. An intention-to-treat analysis was used.



Retention and Adherence

Among the 17 enrolled participants, 75% (6/8) of the intervention condition and 78% (7/9) of the control condition completed the post questionnaire administered 12 weeks after randomization. As noted earlier, an intention-to-treat approach was applied in analyzing the study data. Of the 8 participants who were randomized to the intervention, 5 downloaded the app within 2 days, 2 downloaded it within 13 days but did not use it, and 1 never downloaded it.

App Usage

Among those in the intervention condition who used the app (5 of 8 participants), participants logged their vegetable consumption a mean of 0.7 (SD 0.9) times per day. Daily frequency of vegetable logging over the course of the 6-week intervention period is presented in Figure 2. There was a downward trend in frequency of logging behavior over time, from 0.8 (SD 1.2) times per day during week one to 0.3 (SD 0.6) times per day during week six. There was wide variation in logging frequency among individuals, ranging from 1.2 (SD 1.1) to 0.3 (SD 0.6) times per day.

Vegetable logging occurred during all waking hours, with the greatest proportion of logging taking place during the 1-hour interval after 9 pm (Figure 3). Logging also occurred during all days of the week, with the greatest proportion occurring on Thursdays and the smallest proportion on Wednesdays and Fridays. In examining user logging behavior (ie, the selection of a number of servings consumed per individual vegetable type, such as cucumber), 40% of the time users selected 0.5 servings and 38% of the time users selected 1.0 serving, while all larger serving increments (1.5, 2.0, and so on) were each used less than 9% of the time.

Figure 2. Frequency of vegetable logging among intervention condition, during 6-week intervention period. Day 22 was Christmas Day (Dec 25).

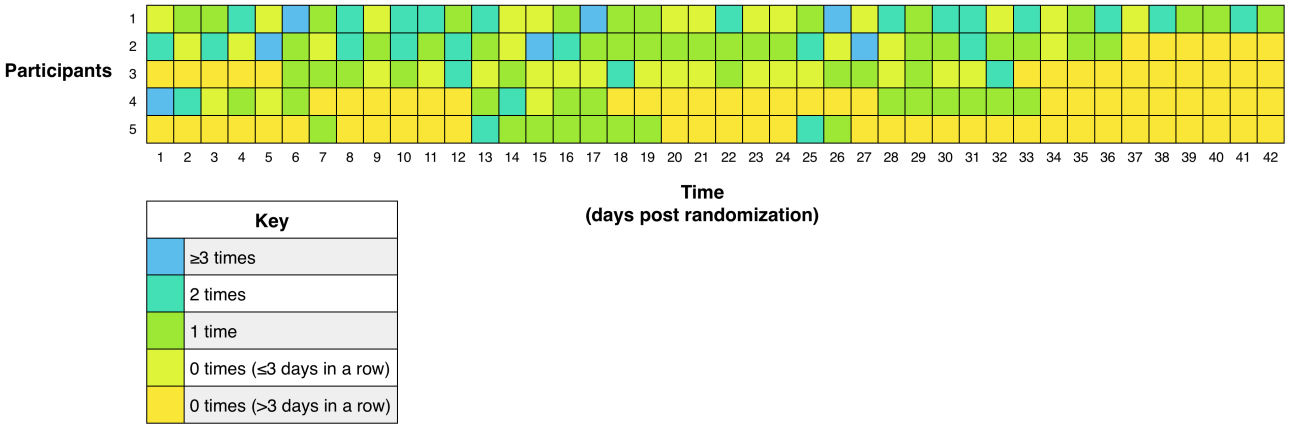
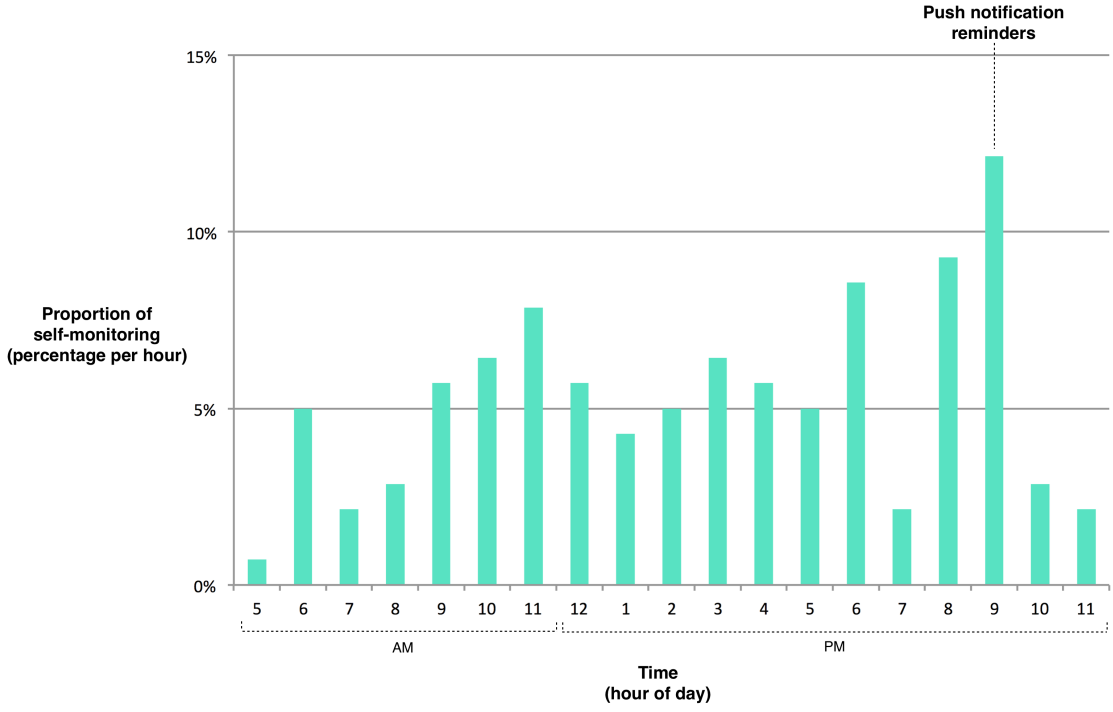


Figure 3. Time of day that users recorded their vegetable consumption using Vegethon. Each hour represents the subsequent 1-hour interval (eg, 5 represents 5:00-5:59 AM). Push notifications were sent at 9 PM as reminders to those who logged the day before but had not yet logged that day.



Vegetable Consumption

Using intention-to-treat analyses, daily vegetable consumption (primary outcome) was found to be significantly greater in the mobile app intervention compared with the control condition at the end of the 12-week pilot study (adjusted mean difference: 7.4 servings; 95% CI 1.4-13.5; *P*=.02). A multiple imputation sensitivity analysis was performed and did not significantly alter these results (*P*=.03). Among secondary outcomes defined a priori, there was significantly greater consumption of green leafy vegetables (adjusted mean difference: 2.6 servings; 95% CI 0.1-5.0; *P*=.04), cruciferous vegetables (1.6 servings; 95% CI 0.1-3.2; *P*=.04), and dark yellow vegetables (0.8 servings; 95% CI 0.3-1.4; *P*=.004) in the intervention versus control condition. There were also statistically non-significant trends toward greater consumption of tomatoes (0.3 servings; 95% CI 0.0-0.6; *P*=.08) and other vegetables (1.7 servings; 95% CI −0.9 to 4.3; *P*=.19) in the intervention versus control condition. Consumption of beans/lentils, which was not targeted by the intervention, was not significantly different (−0.1 servings; 95% CI −0.3 to 0.1; *P*=.37; Figure 4) between the conditions.

Mean baseline consumption of vegetables was comparable in both conditions. The observed means and SD in the intervention condition were 6.0 (SD 2.7) servings at baseline and 13.5 (SD 8.1) servings at 12 weeks. In the control condition, the observed means were 7.0 (SD 5.9) servings at baseline and 3.9 (SD 2.0) servings at 12 weeks. Individual participant changes in consumption from baseline to 12 weeks are presented in Figure 5. Among intervention participants, vegetable consumption increased in 83% (5/6) of participants completing the FFQ, whereas among control participants, vegetable consumption decreased in 71% (5/7) of participants completing the questionnaire.

Figure 4. Differences in vegetable consumption, 12 weeks after randomization (n=17). Adjusted mean difference (circles) and 95% confidence intervals (horizontal lines) between intervention condition (mobile app) and control condition (no mobile app): all vegetables 7.4 (1.4-13.5); green leafy vegetable 2.6 (0.1-5.0); other vegetables 1.7 (−0.9 to 4.3); cruciferous vegetables 1.6 (0.7-3.2); dark yellow vegetables 0.8 (0.3-1.4); tomato 0.3 (−0.04 to 0.6); and beans/lentils −0.1 (−0.3 to 0.1). An intention-to-treat analysis was used, with baseline values carried forward when participants were lost to follow-up. Vegetable consumption was self-reported using an adapted version of the validated semiquantitative Harvard Food Frequency Questionnaire. *P<.05 and **P<.01, based on analysis of covariance predicting post-intervention values, controlling for baseline values.

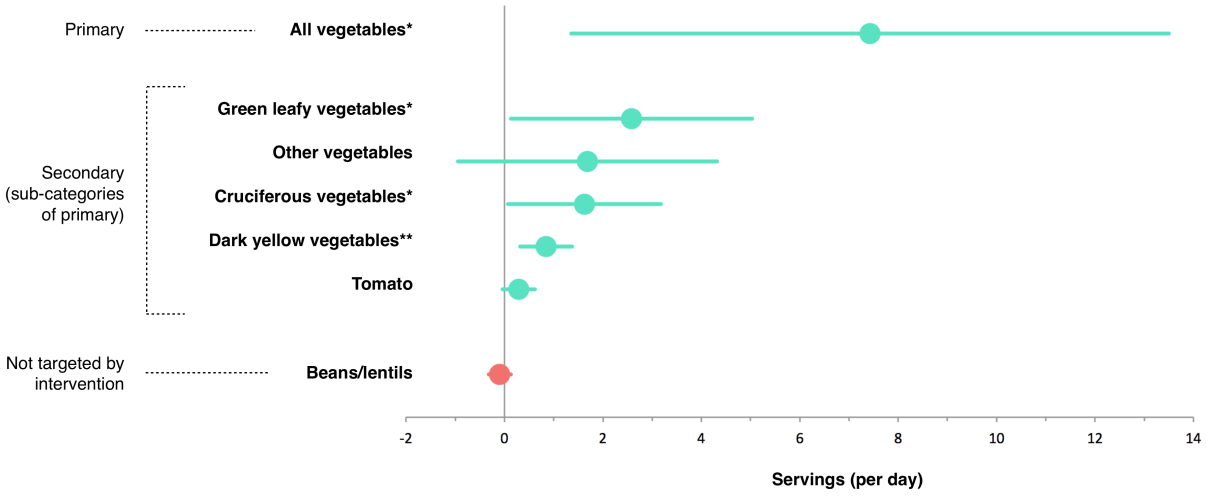
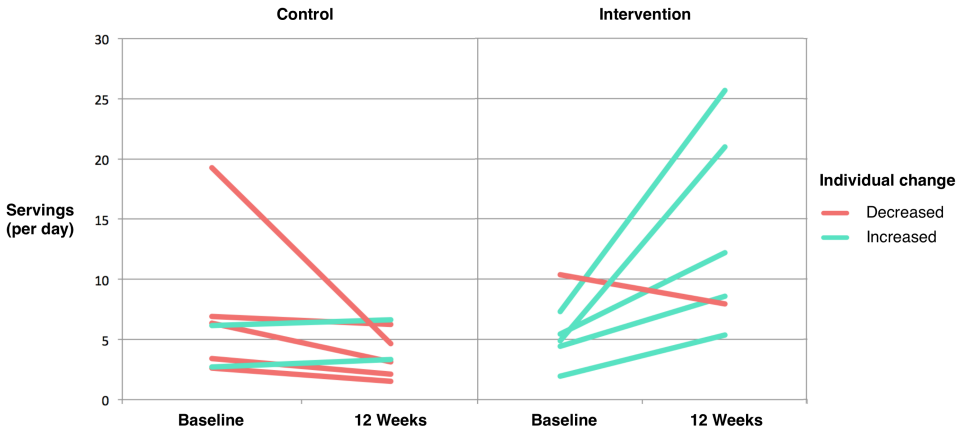


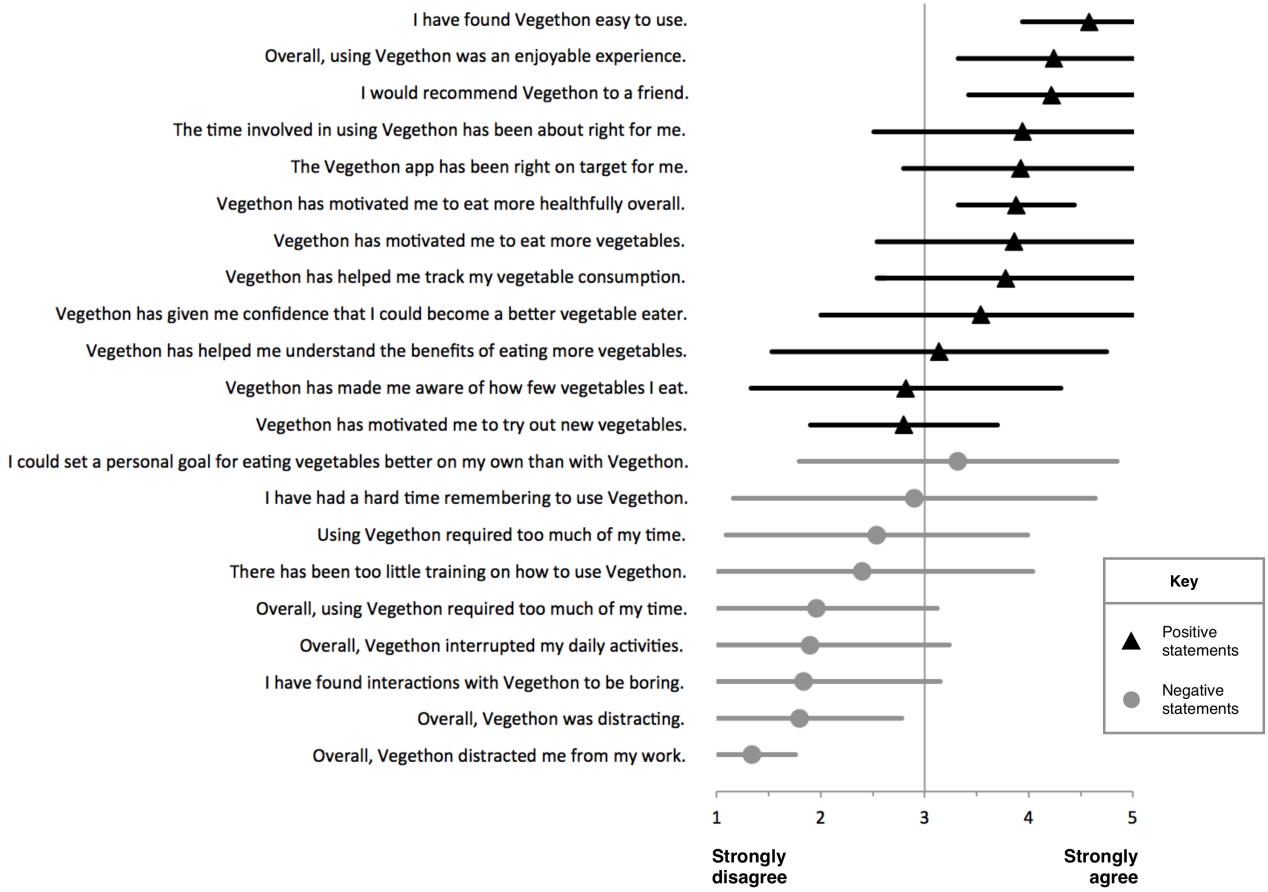
Figure 5. Individual changes in vegetable consumption, from baseline to 12 weeks after randomization (n=13). Vegetable consumption was self-reported using an adapted version of the validated semiquantitative Harvard Food Frequency Questionnaire. This analysis excludes 2 intervention and 2 control condition participants lost to follow-up.



App Usability and Satisfaction

Intervention participants reported positive experiences with the mobile app, including strongest agreement with the following statements: "I have found Vegethon easy to use"; "Overall, using Vegethon was an enjoyable experience"; and "I would recommend Vegethon to a friend" (mean 4.6 (SD 0.6), 4.2 (SD 0.9), and 4.2 (SD 0.8), respectively, on a 1-5 scale, with 5=strongly agree and 1=strongly disagree; Figure 6). Participants reported strong disagreement with the statements "Overall, Vegethon distracted me from my work"; "I have found interactions with Vegethon to be boring"; and "Overall, using Vegethon required too much of my time" (mean 1.3 (SD 0.4), 1.8 (SD 1.3), and 2.0 (SD 1.2), respectively).

Figure 6. Satisfaction with and usability of mobile app intervention. Mean (triangles and circles) and SD (horizontal lines). This exploratory analysis excludes 2 participants who were lost to follow-up and 1 participant who did not use the app. Participants were asked to rate each statement on a 5-point Likert-type scale.



Discussion

Principal Findings

This pilot study aimed to determine the initial efficacy and user acceptability of a mobile app intervention designed to increase vegetable consumption through the creative application of behavior change theory and techniques. Twelve-week testing indicated that Vegethon significantly increased consumption of vegetables, including green leafy vegetables, cruciferous vegetables, and dark yellow vegetables, in the small sample being studied. The mobile app intervention achieved reasonably high rates of engagement and was found to be easy and enjoyable to use by the sample of participants. Increases in vegetable logging observed at 9 pm support the use of push notifications for engaging users. High usage of serving increments "0.5" and "1.0" suggests that the availability of half-serving (vs full serving) increments is appropriate for the logging of individual vegetable types. Given the improved health outcomes associated with increases in vegetable consumption, this pilot study suggests the need for larger, longer-term studies of Vegethon and similar technologies among overweight adults and other suitable target groups.

Comparison with Prior Work

In this first-generation investigation, the mobile app produced relatively large effect sizes, increasing overall vegetable consumption by 7.4 servings. These effects were observed among participants who already had a relatively high baseline vegetable consumption compared with the US national average [14]. The initial effect size observed compares favorably with that of a Web-based intervention in which vegetable and fruit consumption increased by 4.4 servings per day, as assessed by an FFQ [56]. The results also compare favorably with the only other known randomized study of a mobile app targeting vegetable consumption specifically, which was conducted among young adolescent girls [57]. Although the effects are larger than those seen in previous work, it remains difficult to

compare effect sizes given the differences in study outcome measures, study populations, and sample sizes. The theory-driven nature of the app [31], including goal-setting [58] and self-monitoring behavior [37] widely acknowledged to be critical components of behavioral mHealth interventions [59], may have led to greater behavioral changes than observed previously. Overall, these findings align with those found in other investigations of mobile apps to change health behaviors, in which acceptability and initial efficacy have been similarly demonstrated [36].

These results warrant further investigation, as increases in vegetable consumption may lead to changes in overall diet composition and weight loss, even in the absence of specific guidance to decrease consumption of other foods [60]. For example, in a study among overweight adults by Norman et al [61], a short message service intervention that increased vegetable consumption led to weight loss. Such interventions that focus on the inherent benefits of the target behavior itself (eg, increasing vegetable consumption) may lead to more sustained behavior changes than those focusing on longer-term goals (eg, weight loss) [40]. Given the high and growing prevalence of overweight in the United States [62], and the fact that people in higher weight categories are more likely to develop chronic diseases associated with excess weight [63], strategies to reduce modifiable risk factors including diet among overweight adults are needed [62,63]. This study demonstrating the initial efficacy of a mobile app to improve diet among highly motivated overweight adults presents one such possible strategy that warrants further investigation.

Strengths

Among the strengths of this pilot investigation were the theory-based development of the app that helped to ensure it would be engaging to use for the target population as well as the randomized controlled study design that is relatively rare in the mHealth field, in which few technologies are evaluated with rigorous study designs. Pilot randomized controlled trials represent an important phase in the iterative development of effective digital health interventions [64], particularly in the context of the mHealth landscape where developers often skip outcome evaluations altogether, threatening progress in the field [65]. This stand-alone mHealth app was evaluated in the context of an intensive weight loss trial, in which consumption of high-quality whole foods and vegetables was emphasized. The efficacy of the app beyond the effect of the parent trial suggests the potentially high degree of potency of the mobile app intervention, at least during initial use. These effects may be due to the advantages inherent to mobile phone-based interventions, including timely feedback, personalization, and daily interaction [18], as well as the theory-driven nature of the intervention.

Limitations

There were several methodological limitations to this pilot study. The participants were concurrently enrolled in a weight loss trial and were interested in helping shape the development of mobile technology. Generalizability of these findings to other samples that are not enrolled in a weight loss trial and/or are not as highly interested or motivated to use a mobile app to increase their vegetable consumption is unknown. The loss of 4 participants to follow-up in this short study may have resulted from the high volume of time-intensive tasks (eg, classes, blood draws, questionnaires) simultaneously required of participants by the parent trial. Further studies are indicated to evaluate the efficacy of the app among participants outside of the context of a weight loss intervention who may respond to different types of motivation.

As with all dietary assessment methods, there were inherent limitations to the adapted Harvard FFQ measurement tool used, including reliance on self-report, which could have led to a response bias (eg, participants randomized to the app simply reporting greater vegetable consumption at follow-up versus actually consuming more vegetables). Moreover, the FFQ has been acknowledged to overestimate intakes, particularly for foods consumed rarely and perceived as healthy (eg, vegetables) [66,67]. Despite the high test-retest reliability of the FFQ over time in the control condition and in measures not targeted by the intervention (eg, bean intake), the observed effect size for the primary outcome was notably large. Although the hypothesis was supported, alternative explanations may include that the use of Vegethon caused participants to become more attuned to their vegetable consumption, more aware of the vegetables they consumed in other foods, and/or more accurate or exaggerated reporters of their vegetable consumption.

The small sample size of this study allowed only an imprecise estimate of the effect size for vegetable consumption and prevented analysis of potential mediators and moderators. Studies in other areas have found that the effect sizes of small initial studies in an area often tend to be larger than those found in subsequent larger studies [68]. A larger study is indicated to more precisely estimate differences in vegetable consumption and to assess mediators and moderators of observed changes in dietary behaviors. The 12-week duration of this pilot study provides an assessment only of short-term effects, and a longer trial is warranted to determine whether the observed effects are sustained over a longer period of time.

Conclusions

The study results suggest that a theory-based mobile app may be a feasible way to increase vegetable consumption among adults attempting to lose weight, at least in the short term. These findings support the need for theory-driven mobile technologies to more effectively produce improvements in health behaviors. Larger-scale and longer trials are necessary to fully evaluate the potential of Vegethon and similar technologies to produce sustained increases in vegetable intake as well as weight loss and other associated health benefits among overweight adults.

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Authors' Contributions

SAM designed the study, developed the intervention, managed data collection, conducted statistical analyses and interpretation, and wrote the manuscript. MM helped develop the intervention, performed randomization, conducted statistical analyses, and provided feedback on the manuscript. SS, CDG, and AK contributed guidance and consultation throughout the study and provided feedback on the manuscript. CDG provided the study location and access to parent trial participants and data. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH Checklist.

[PDF File (Adobe PDF File), 4MB - mhealth_v4i2e51_app1.pdf]

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Abbreviations

ANCOVA: analysis of covariance
App: mobile application
BMI: body mass index
CI: confidence interval
CONSORT: Consolidated Standards of Reporting Trials
FFQ: food frequency questionnaire
mHealth: mobile health
SD: standard deviation
SPSS: Statistical Package for the Social Sciences
US: United States
USDA: United States Department of Agriculture

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Original Paper

User Preferences for Content, Features, and Style for an App to Reduce Harmful Drinking in Young Adults: Analysis of User Feedback in App Stores and Focus Group Interviews

Joanna Milward[1], MSc; Zarnie Khadjesari[1], PhD; Stephanie Fincham-Campbell[1], MSc; Paolo Deluca[1], PhD; Rod Watson[2], MPH; Colin Drummond[1], MD FRCPsych

[1]Addictions Department, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, United Kingdom

[2]Health Innovation Network, London, United Kingdom

Corresponding Author:
Joanna Milward, MSc
Addictions Department
Institute of Psychiatry, Psychology and Neuroscience
King's College London
ASB, 4 Windsor Walk
Denmark Hill
London, SE58BB
United Kingdom
Phone: 44 2078480717
Fax: 44 2078480717
Email: joanna.milward@kcl.ac.uk

Abstract

Background: Electronic screening and brief intervention (eSBI) is effective in reducing weekly alcohol consumption when delivered by a computer. Mobile phone apps demonstrate promise in delivering eSBI; however, few have been designed with an evidence-based and user-informed approach.

Objective: This study aims to explore from a user perspective, preferences for content, appearance, and operational features to inform the design of a mobile phone app for reducing quantity and frequency of drinking in young adults engaged in harmful drinking (18-30 year olds).

Methods: Phase 1 included a review of user reviews of available mobile phone apps that support a reduction in alcohol consumption. Apps were identified on iTunes and Google Play and were categorized into alcohol reduction support, entertainment, blood alcohol content measurement (BAC), or other. eSBI apps with ≥18 user reviews were subject to a content analysis, which coded praise, criticism, and recommendations for app content, functionality, and esthetics. Phase 2 included four focus groups with young adults drinking at harmful levels and residing in South London to explore their views on existing eSBI apps and preferences for future content, functionality, and appearance. Detailed thematic analysis of the data was undertaken.

Results: In Phase 1, of the 1584 apps extracted, 201 were categorized as alcohol reduction, 154 as BAC calculators, 509 as entertainment, and 720 as other. We classified 32 apps as eSBI apps. Four apps had ≥18 user reviews: Change for Life Drinks Tracker, Drinksmeter, Drinkaware, and Alcohol Units Calculator. The highest proportion of content praises were for information and feedback provided in the apps (12/27, 44%), followed by praise for the monitoring features (5/27, 19%). Many (8/12, 67%) criticisms were for the drinking diary; all of these were related to difficulty entering drinks. Over half (18/32, 56%) of functionality criticisms were descriptions of software bugs, and over half of those (10/18, 56%) were for app crashing or freezing. Drinksmeter and Alcohol Units Calculator were the most highly praised apps overall (23/57 and 22/57; 39% of praise overall). In Phase 2, two main themes were identified. The meaningfulness theme reflected how young adults thought apps needed to be tailored to the interests and values of their age group, particularly emphasizing content and feedback around broader health and well-being factors such as exercise, diet, and image. The community theme suggested that young adults want to be able to engage with other app users, both in groups of friends and with online users for motivation and support.

Conclusions: Targeted and relevant information and feedback, in addition to easy-to-use monitoring tools, were found to be important features of a mobile phone app to support a reduction in drinking. Future app development should consider tailoring all app aspects to the needs of young adults, considering broader well-being monitoring tools and online community functions.

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KEYWORDS

alcohol; drinking; young adults; mhealth; brief intervention; apps; smartphone; digital; focus group

Introduction

The Internet has been found to be an effective vehicle for the delivery of screening and brief intervention (SBI) to reduce alcohol consumption. Meta-analyses demonstrate electronic SBI (eSBI) to be effective in reducing alcohol consumption by 1-2 drinks per week after 6 months compared to controls [1,2]. eSBI delivered via mobile phone, tablet, or computer can be delivered discreetly and flexibly to large numbers of the population in need at a competitive cost, without reliance on the time of health care staff, with whom there are well-recognized barriers to implementation [3,4]. Research suggests that eSBI is the preferred delivery medium for alcohol SBI in young adults [5].

The ubiquity of mobile phones provides a further vehicle for the delivery of eSBI via digital apps. It is estimated that at least 76% of young people aged 15-34 own a smartphone in the United Kingdom [6], with 77% of young people who own a smartphone using apps, the highest among all age categories [7]. However, nearly 90% of alcohol-related apps available to download encourage alcohol consumption, for example through drinking games [8], with few alcohol apps that use evidence-based behavior change techniques (BCTs) to target harmful alcohol use [9,10].

Developing effective and engaging eSBI apps is a new challenge for researchers. Few randomized controlled trials of alcohol apps, as opposed to Internet-delivered SBI, have been published, and those that have provide ambiguous evidence on their effectiveness to reduce alcohol consumption, with studies reporting reductions, increases, and no-change in alcohol consumption [11-13]. A major issue with app development is sufficiently engaging the target population with the app content and features: while app usage continues to rise [14], 95% of apps are not used more than a month after download [15].

For an app designed to support a reduction in drinking, it is important to look to the informatics field for guidance on developing apps. User-centered design (UCD) [16] is a systematic app development method that focuses on the relevance, needs, and preferences of the target user. UCD involves consideration of the user at every stage of the design process including iterative cycles of focus groups, prototyping, and user testing.

Previous research has focused on alcohol apps' adherence to evidence-based guidelines or app effectiveness in reducing drinking [9-11]. To the authors' knowledge, no research has explored the preferred content of alcohol apps from a user perspective. The aim of this study is to determine preferences for content, visual appearance, and operational features to inform the development of an eSBI app targeting harmful drinking young adults.

The specific objectives addressed by this paper were to (1) quantitatively identify which eSBI app content, operational features, and esthetics were highly rated, criticized, and in need of improvement, through a content analysis of user feedback, and (2) qualitatively identify the preferences for content, operational features, and esthetics of young adults who drink harmfully, through focus groups.

Methods

Phase 1

Review of User Reviews of Alcohol eSBI Apps

The Apple iOS (mobile operating system) and Google Play platform allow users to download apps, assign a star-rating, and provide review comments. User reviews provide an important source of feedback for app developers and prospective app purchasers, typically containing positive and negative feedback on content, functionality, and quality of the app [17,18]. These user reviews provide a rich source of information to support app development from a user perspective and are a key measure of the app's success [19].

Search Strategy and Data Extraction

Alcohol-related apps were extracted from the UK versions of Google Play and iTunes in April and May 2015 with the following search terms: "alcohol," "drink less," and "reduce drinking." Search terms were based on those used in previous research [9], as well as additional terms suggested by members of the wider alcohol research team in the Addictions Department at King's College London. The first 200 apps for each search term were extracted [9], which were presented in rank order. App name, price, ranking in search results, and number of user reviews were extracted.

Apps were considered eligible for inclusion if they were categorized as an eSBI app and their aim were to help users monitor and cut down their alcohol use. The objective of the paper was to inform the development of an electronic brief intervention for harmful drinkers; therefore, apps targeting dependent drinkers were excluded.

In Stage 1, apps extracted from the initial search were categorized from the description of the app provided by the developer as targeting alcohol reduction support, blood alcohol content (BAC) calculators, entertainment (drinking games, cocktail recipes, bar and restaurant finders), or other (all apps that had no content relating to alcohol, eg, Candy Crush, non-English apps, and apps for educational purposes such as apps for mental health professionals).

In Stage 2, eSBI apps were extracted from the alcohol reduction support category. The aim was to broadly include apps that included SBI components such as alcohol monitoring, goal setting, and normative feedback [20]. Apps were excluded if they used non-evidence-based methods for alcohol

monitoring/support/reduction such as hypnosis and magic spells; were targeted at dependent drinkers; were eBooks/magazines/quotes; targeted multisubstance abuse or drugs; targeted a specific group (such as pregnant women); or claimed to provide alcohol therapy or counseling.

In Stage 3, apps were excluded if they duplicated across the same platform (ie, appeared more than once in the initial search across Google Play). Duplicate apps across the two search platforms (eg, Google Play and iTunes) were not excluded as the user reviews are different for each platform and could be included in analyses. Apps with no user reviews were excluded.

Analysis of User Reviews

Each app was coded for content. A researcher downloaded the app onto an iPhone 6 and categorized each feature targeting alcohol monitoring and reduction support. Content analysis was used to code the app review content in order to create a quantitative description of the text [21]. The coding scheme for the user feedback review was adapted from themes identified in a previous review of app user feedback, developed by Pagano and Maalej [22], and through pilot coding of a random sample of 42 app user reviews. If any new codes emerged from the data, these were incorporated into the coding scheme. Each user review was then independently coded by 2 reviewers (JM and SFC) using the deductive coding scheme. The 2 coders had an 81% agreement rate across the coding categories. All discrepancies were discussed until 100% agreement was reached.

Phase 2

Focus Groups

Design and Setting

Focus groups were chosen as the most appropriate method of data collection as they allow for a multiplicity of views to be shared, developed, and discussed, as well as allowing for consensus on a topic to be explored, which is not possible with a one-to-one interview qualitative design. Four focus groups were conducted at the Denmark Hill Campus of King's College London. Ethical approval was obtained from the University Ethics Committee (ref. number HR14/150453).

Facilitators

Two members of the research team (JM, ZK, and RW) facilitated each focus group. The facilitators all have a background in delivering SBI and experience with developing electronic health interventions. All facilitators were experienced in conducting focus groups.

Participants

Young adults, aged 18-30 years who lived in South London and scored 16+ on the alcohol use disorders identification test (AUDIT) [23], a validated measure of alcohol consumption and related harm, were eligible to participate in the study.

Recruitment

Participants were recruited via paid online advertisements through Facebook (an online social networking website) and Gumtree (a free online classified advertising and social community website). The advertisements invited potential participants to take part in a focus group that would review different mobile phone apps available to help young adults reduce their alcohol use and examine how they could be improved. A link was provided on the advertisement that accessed an online prescreening survey. Potentially eligible participants completed the AUDIT as well as providing information on age, contact details, and address.

All potential participants who met the inclusion criteria, that is, aged 18-30, living in South London, and drinking at a level considered harmful (16+ on the AUDIT), were invited to participate in a focus group. Participants received £30 in High Street vouchers as compensation for their time. Travel expenses were recompensed.

One week before the focus group, participants were asked to download a specific eSBI app (selected from those with the most user reviews) and use it over the course of a week, thinking about what they liked and disliked about the app.

Data Collection

Written informed consent was obtained before commencement of the group. The facilitators introduced the project, outlined the aims, and highlighted the ground rules of confidentiality and mutual respect. Each focus group lasted for approximately 1.5 hours.

Semistructured topic guides were used to frame the group discussion. The first half of the focus group explored what participants liked and disliked about the app they had reviewed. This discussion was broadly organized by the topics of content, functionality, esthetics, information on drinking, and how the app could be improved. The second half of the focus group discussed the type of features the participants might include if they were designing their own eSBI app to help young adults reduce their alcohol use.

Data Analysis

Focus groups were recorded and transcribed verbatim by a professional transcription company. All data were coded using NVivo qualitative data analysis software (QSR International Pty Ltd. Version 10, 2012). A detailed thematic analysis was undertaken [24]. Both an inductive and deductive approach were used, incorporating the major themes (codes) from the app review as well as any additional themes emerging from the data. The transcripts were read through several times and coded deductively using the coding framework from the app review as well inductively for new themes. The codes were then systematically organized into broader themes and subthemes and re-examined by going back and forth between the data and the coding framework.

Results

Phase 1: Review of User Reviews of Alcohol eSBI Apps

Description of Apps

Of the 1584 apps extracted in the search, 154 were categorized as BAC calculators, 509 as entertainment apps, and 720 as other (see Figure 1). We categorized 201 apps as targeting alcohol

monitoring and reduction. After excluding multisubstance-use apps, non-SBI apps, and duplicates across platforms, 37 apps remained (32 unique apps when excluding duplicates between platforms). Of the unique apps, 69% (22/32) were free apps. Nineteen of the apps had one or more user reviews. The majority of apps had low numbers of reviews (range 1-114, mean 18.0 reviews, SD 31.24); 74% (14/19) had 1-10 reviews, 5% 11-17 (1/19) and 21% had ≥18 (4/19). As the user reviews were typically brief, consisting of a few sentences of feedback, apps were included that had more than or equal to the mean number of reviews (mean 18) to provide sufficient data to conduct a content analysis.

Four unique apps were identified for final analysis: Drinkaware (114 reviews); NHS Change for Life (C4L) Drinks Tracker (95 reviews); Drinksmeter (21 reviews), and Alcohol Units Calculator (AUC, 18 reviews). The 18 most recent reviews were included, resulting in a total of 72 individual app user reviews for analysis. Drinksmeter had the highest user-rating out of five stars overall (mean 4, SD 0.3), followed by AUC (mean 3.6, SD 1.5), Drinkaware (mean 3.1, SD 1.30), and C4L with the lowest (mean 1.7, SD 1.1).

The apps varied in complexity and sophistication of content (see Table 1); however, all included at minimum a daily drinks tracker with graphical feedback on units (except Drinksmeter, which requested drinking level over the previous week only). Excluding AUC, all apps provided information on drinking risk level and recommended limits. C4L and Drinksmeter provided tips and advice for cutting down. Drinkaware and Drinksmeter provided feedback on calories, costs, and equivalents in unhealthy food. Drinksmeter provided normative feedback on weekly alcohol consumption, included a risk adjuster for mental health, medication, and drug use as well as administering the AUDIT and providing feedback. Drinkaware had additional features including the option to set goals, create “weak spots” via GPS data on the phone and information on alcohol support services.

Table 1. Description of app features.

Feature included	Drinkaware	Drinksmeter	AUC	C4L
Drinks tracker (daily)	Yes	No	Yes	Yes
Drinks tracker (previous week)	Yes	Yes	Yes	Yes
Information on drinking risks	Yes	Yes	No	Yes
Information on guidelines	Yes	Yes	No	Yes
Information on support services	Yes	No	No	No
Advice for cutting down	No	Yes	No	Yes
Normative feedback	No	Yes	No	No
Feedback: calories, costs, food	Yes	Yes	No	No
Risk adjuster	No	Yes	No	No
AUDIT	No	Yes	No	No
Goal-setting	Yes	No	No	No
Weak spots	Yes	No	No	No

Categories

A content analysis was performed based on the five primary coding categories defined in Table 2. All primary codes were subsequently coded into subcategories and then coded as either praise, criticism, or recommendation statements. A total of 194 meaning units were identified. Key findings are reported here (see Table 3 for a full breakdown of coding).

Figure 1. Flow diagram of apps selected for coding.

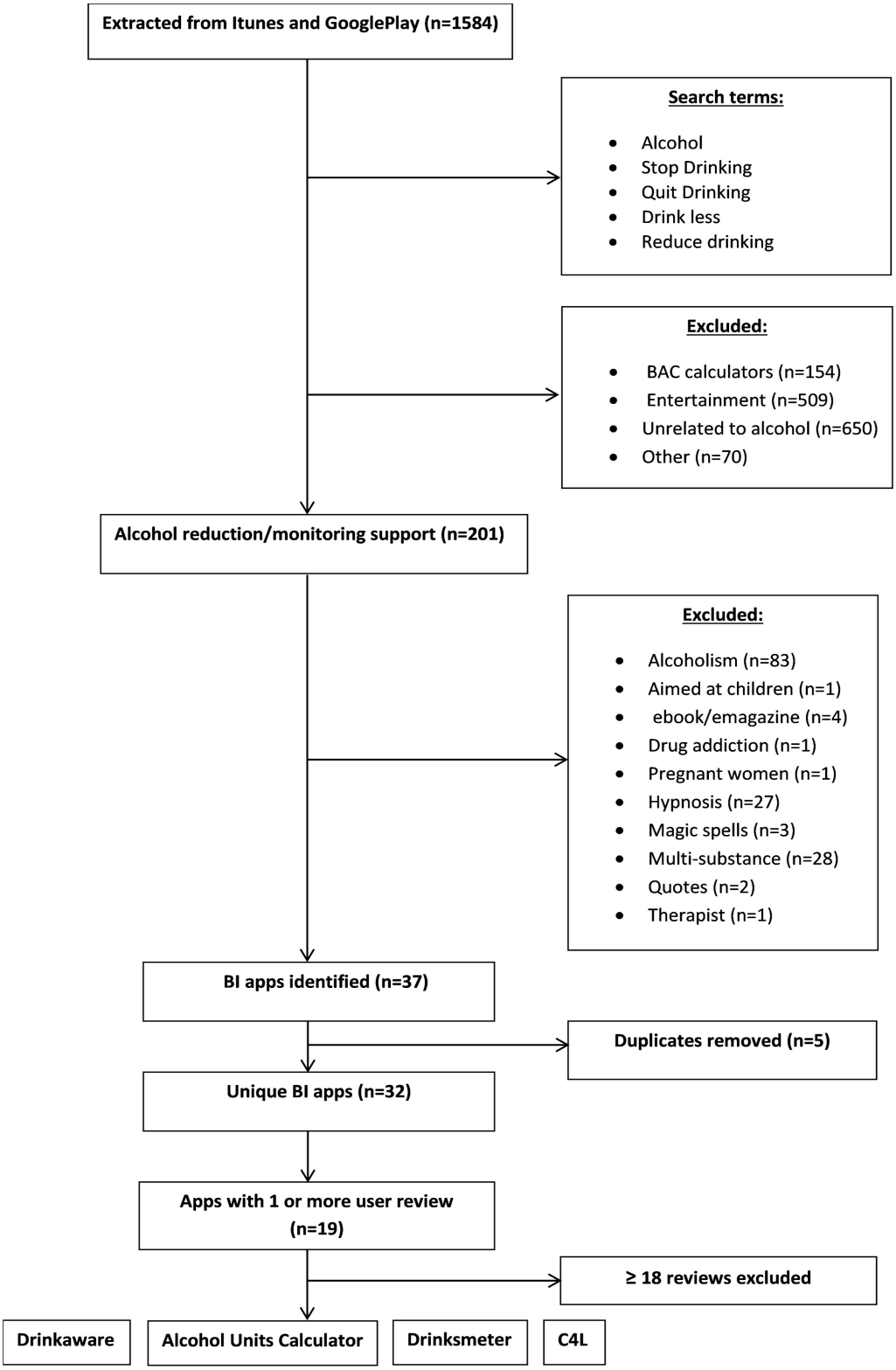

Table 2. Description of coding categories.

Category	Categorized references, n	Definition	Examples
Content	60	All text relating to content and features of the app such as the drinks diary, graph, and information provided.	"Only improvement would be to have the line graph over 28 days instead of just 7 days."
Functionality	43	All text relating to operational features of the app such as saving, entering, and loading data. Descriptions of software bugs.	"Doesn't work properly. Can't get beyond the daily input page to see totals or goals etc"
Esthetics	7	All text relating to the visual appearance of the app.	"Plus points—Jazzy colour scheme—arguably prettier than the earlier more functional design"
General comments	24	All text relating either praise or criticism of the app that was non-specific.	"Great app"
Other	60	All content not relating to a topic above, eg, descriptions of app and usage patterns, who the app would benefit, questions to other users and developers, jokes, noise.	"Am a GP. Use this with my patients."

Content Category: What Users Liked (Praise)

Nearly half (27/60, 45%) of references in the content category were praise for the apps. The highest proportion (12/27, 44%) was praise for the information and feedback provided in the apps, followed by praise for the drinks diary features (5/27, 19%).

Drinksmeter had the highest proportion of praise references for the information and feedback it provided (10/12, 83% of praise references). AUC was the most praised for its monitoring features (10/12, 83% of praise references for monitoring). Drinksmeter and AUC had the highest proportion of praise references for content overall, both with 41% (11/27) of praise references. C4L was the least praised in terms of content with 4% (1/27) of content praise references.

Content Category: What Users Disliked (Criticisms)

One-fifth of all content references were criticisms (12/60, 20%). The majority (8/12, 67%) were for the drinking diary. All of these criticisms were related to difficulty entering drinks, such as apps not providing enough brands or drink choices to enter consumption level, limited drink size choices, limited options to enter alcohol strength (Alcohol by Volume [ABV]), and not being able to enter more than one drink at a time.

Drinkaware received the highest proportion of content criticisms overall with 50% (6/12) of references. C4L received 42% (5/12) of content criticisms and AUC 8% (1/12). Drinksmeter did not receive any criticisms for content.

Content Category: Recommendations for Improvement

Thirty-five percent (21/60) of content references were recommendations. 62% (13/21) were recommendations for improvement of the drinking diary, followed by 24% (5/21) for the graph function (which tracks alcohol use over previous week/month). The most frequently cited recommendations were for functions to enter specific ABV values (4/21, 19%), followed by being able to store favorite drinks (3/21, 14%).

Table 3. Coding frequencies by category.

Category	Praise frequency, n (%)	Criticism frequency, n (%)	Recommendation frequency, n (%)
Content (overall)			
Goal setting	0 (0)	0 (0)	1 (5)
Information	12 (44)	3 (25)	2 (10)
Monitoring-drinks diary	5 (18)	8 (67)	13 (62)
Monitoring- graph	3 (11)	0 (0)	5 (24)
Monitoring-general (praise/criticism)	4 (15)	0 (0)	0 (0)
Positive reinforcement	0 (0)	1 (8)	0 (0)
Reminders	1 (4)	0 (0)	0 (0)
Rewards	1 (4)	0 (0)	0 (0)
Tone	1 (4)	0 (0)	0 (0)
General praise/criticism	0 (0)	0 (0)	0 (0)
Total	27 (100)	12 (100)	21 (101)
Functionality (overall)			
Data-entering	0 (0)	1 (3)	0 (0)
Data-losing	0 (0)	4 (13)	0 (0)
Data-saving	0 (0)	3 (9)	0 (0)
Data-importing or exporting	0 (0)	0 (0)	2 (66)
Description of bug	0 (0)	18 (56)	0 (0)
Processing speed	0 (0)	3 (9)	1 (33)
General praise/criticism	8 (100)	3 (9)	0 (0)
Total	8(100)	32 (99)	3 (99)
Esthetics (overall)			
Color	2 (50)	0 (0)	0 (0)
Text	0 (0)	1 (33)	0 (0)
General praise/criticism	2 (50)	2 (66)	0 (0)
Total	4 (100)	3 (99)	0 (0)
General comments	18(100)	6 (100)	0 (0)

Functionality Category: What Users Liked (Praise) and Disliked (Criticisms)

No users praised specific components of the functionality of the apps. Eight unique references (100% of functionality praise references) praised general functionality components. Due to the small sample size, this was not examined between apps.

The majority of criticism references (18/32, 56%) were related to descriptions of bugs in the software. The most commonly criticized bugs were issues relating to the app crashing or freezing (10/18, 56%).

Esthetics Category

Relatively few users reported on esthetics across the four apps. There were 7 references in total; these were mostly split over general praise comments (29%) and general criticisms (29%).

Most Liked and Disliked Apps

All of the praise and criticism references across the three categories (content, functionality, and esthetics) were aggregated.

There were 57 praise references overall (43% of all references in total). Drinksmeter and AUC received the most praise with 40% (23/57) and 39% (22/57) respectively, followed by Drinkaware with 14% (8/57).

There were 53 criticisms overall (40% of all references in total). Both Drinkaware and C4L received considerably more criticism (24/53, 45%, and 21/53, 39%, respectively) than Drinksmeter and AUC (2/57, 4% and 6/57, 11%) respectively.

Phase 2: Focus Groups With Young Adults Engaged in Harmful Drinking

Recruitment

A total of 200 people completed the online screening survey; 117 from an advertisement placed on Gumtree, 83 via Facebook. In total, £80 was spent on Gumtree recruitment and £100 on Facebook recruitment. The advertisement invited anyone who drank alcohol to participate in a focus group about mobile phone apps for drinking reduction. Nearly three-quarters (146/200, 73.0%) were female. Over half (105/200, 52.5%) were employed (full-time or part-time), 22 were unemployed (11%), and 73 were students (37%). Of these, 81 (40%) had a self-reported score of 16 or more on the AUDIT, were between 18-30, and lived in South London. In total, 36 eligible participants signed up to one of the four focus groups.

Participant Characteristics

Twenty-one participants attended one of four focus groups over a 1-month period in June-July 2015. Of the 21 participants, 18 (86%) were female, 12 (57%) were employed, 7 (33%) were students, and 2 (10%) were unemployed. The mean AUDIT score across the participants was 20 (SD 5.0).

App Selection

The apps were selected based on the four apps identified in the user app review (Drinkaware, Drinksmeter, C4L, and AUC). Only free apps were included in the analyses. Drinkaware was randomly selected to be reviewed twice. C4L was reviewed by 4 participants, Drinkaware by 10 participants, and Drinksmeter by 7 participants.

Young Adults' Views on the Development of an ESBI App to Target Harmful Drinking

Two main themes emerged from the data: the theme of meaningfulness and the theme of community. Key findings are reported below. See Table 4 for a detailed breakdown of themes.

Meaningfulness

The meaningfulness theme broadly describes the opinion of the participants that an approach that tailors all content and features to the target user is inherent to any successful eSBI app. The "meaningfulness" theme is divided into three further subthemes: information and feedback, goals, and monitoring.

Information and Feedback

The majority of participants felt that the information and feedback provided to young adults about drinking was often not meaningful. For example, government drinking guidelines (eg, recommended unit consumption) and information on risk categories (such as "high risk") were felt to be unrealistic and irrelevant to the participants:

> *Well also the levels…I know it's the government levels and the medical stuff but like nobody sticks to them. Well obviously some people do. So, you know, you put in a couple of drinks for two nights and you're already increasing or higher risk or something, which is unrealistic. A normal night for normal people is high risk, well that's not going to help me, I don't think, because that's standard. So I think just to monitor your drinking and stuff, fine, but I think if you actually want to use it to cut back, just saying you're at higher risk, well that's meaningless because everybody I know is.*

Table 4. Description of main themes and subthemes from focus groups.

Themes	Description	Subthemes 1	Description	Subthemes 2	Description
Meaningfulness	Apps need to be designed as meaningful and tailored to young adults.	Risk categories and government recommendations	Young people felt that government guidelines are unrealistic in light of UK drinking cultures.	n/a	n/a
		Information and feedback	Must provide information and feedback which is interesting to young people.	Wellness and lifestyle	Young adults are interested in factors such as weight gain; exercise; calorie and sugar content; impact upon image; junk food and exercise equivalents; costs; physical, psychological, and social impact; positive information; safety tips and sober things to do.
		Information and feedback	See above.	Personalization and tailoring	Information and feedback needs to be tailored to users' demographics. Users would like to be able to set up own information preferences.
		Information and feedback	See above.	Presentation	Information needs to be succinctly displayed, not wordy, bullet-pointed, easy to read. Users would like the option of information pop-ups.
		Goals	Goals should be meaningful to young people, focus on short-term and long-term health risks and include lifestyle and wellness goals.	Personalization and tailoring	Set own goals and write personalized messages to yourself for motivation. Personalize timings and frequency.
		Goals	See above.	Prompts for goals	Option to set up reminders for goals at important times, eg when on a night out.
		Monitoring	Monitoring features should include a drinks diary and graph.	Drinks Diary	Data should be easy to enter including prompts and reminders; more choices of brands and drinks; barcode scanner.
		Monitoring	See above.	Graphs	Plot other health/well-being information that is relevant to drinking, eg mood; costs, and events.
		Esthetics	Young people wanted an app that was stylish and well-designed, with options to personalize and tailor the look of the app. They also requested the option to set up a user profile.	n/a	n/a

Themes	Description	Subthemes 1	Description	Subthemes 2	Description
Community	Creating an online community of young people who want to reduce their drinking.	Support and motivation	The most successful way to cut down drinking is with the support of other people. This should be integrated into apps for young people.	n/a	n/a
		Group goals	Feature that allows an individual user to join an online group and work towards a specific goal, eg, "spend less money on alcohol" or "have a drink-free weekend".	Friends	Users should be able to set goals with groups of friends.
		Group goals	See above.	Online users	Users should have the option to join online groups with a dedicated goal via a goals "forum".
		Autonomy and privacy	Group goals should be opt-in and users can choose to set up private goals only.	n/a	n/a

One reason for the information not being meaningful to the participants was that because episodic binge-drinking among young people is perceived as such a socially accepted and entrenched activity, the drinking guidelines are thought to be unachievable and consequently not relevant to young people.

Another frequently cited reason was that the information and feedback on risks provided by the apps was generic and not tailored to specific target groups. Participants discussed how important it was for information and feedback to be tailored to them as individuals, making it more relevant to them:

> *I don't know how to put it. It's not that I disagree with it, it's just that I understand that it's taken from data over like millions of people potentially and that an individual is very different to a million people, and some people have a great capacity for drinking huge amounts and being absolutely fine.*

On the other hand, apps that the participants praised the most for information and feedback (such as Drinksmeter) provided feedback on broader lifestyle and well-being factors such as exercise, alcohol-related weight gain, and the sugar content of drinks:

> *Having something other than the units like calories or sugar that you're interested in, because 'unit' isn't really a big factor for some people, like for me it's not something I would count or particularly are worried about, so to use it I would need another factor.*

This was a common theme throughout the focus groups. While participants were aware that heavy drinking put them at a higher risk of a variety of health problems, they also explained how, as young people, it was difficult to relate to such long-term health warnings. The shorter-term effects of alcohol on factors such as lifestyle and well-being, which young people value, would provide more motivation to cut down. Indeed, the effects of alcohol on participants' physical looks were a key factor in making young people think about reducing their drinking:

> *It would say what I'm going to look like in five years, what I'm going to look like in ten years, because people are a bit vain as well, if you play into that. If it can show me if I drink at this level what I'm going to look like because of it in five or ten years that would probably make me cut down. That would probably make me be a bit healthier.*

While participants did think it necessary to provide information and feedback on the negative consequences of drinking, in particular providing more "shocking" information similar to smoking health campaigns, the participants also reported wanting positive information on the benefits of not drinking

> *Yes, so giving people positive reasons not to drink and then negatives; like negative reasons would be: it's bad for your health; you spend too much money. Positive things would be: you can achieve more in sports in fitness; you feel more confident.*

Again, this links into the concept of wellness, in that reducing drinking is a broader lifestyle change undertaken to improve the quality of a person's life in a variety of ways, from being able to exercise more, be more efficient at work, have fewer hangovers and improve their mental and physical health.

Goals

For the participants, being able to set personalized goals that were meaningful to them as individuals was paramount to successful alcohol reduction. Often participants would report that setting goals purely to reduce the number of units of alcohol consumed per week was not enough motivation for them to cut down.

> *I think then it's making it a bit more than just a drinking app; there's not that much incentive to cut down on drinking but when you make it more about your whole lifestyle then you are more likely to use it.*

All participants suggested that users need to be able to set their own goals and reminders and be able to write themselves personalized messages for motivation. This included goals around other issues related to alcohol such as calories and costs:

> *It's about creating something that people are actually going to use, not just bored with it or annoyed with [it], it's something that's got to be relevant. Like being able to set your own goals and potentially put your own messages on it…Being able to put a message into this app to remind me, "Just don't have a drink tonight because you're doing this tomorrow and you've already spent 'x' amount this week might be quite good."*

Once again, goals linked into the concept of wellness and lifestyle, making alcohol reduction a channel through which to improve overall quality of life. For it to be meaningful to the participants, they must be able to tailor their goals to their priorities of what they want to achieve.

Monitoring

Consistently reported by participants was that all of the apps made it difficult to enter drinks into the drinks diary. This was typically because the apps were not designed around the drinking habits of young people. For example one female participant, talking about the C4L app, reported that it did not include the types of drinks that she consumed:

> *I was inputting that I had had some cider and I couldn't remember what strength it was, I knew it was a strong cider and I don't know if I've used the same app as you guys, 'My Fitness Pal' but I had a diet and exercise app that had like actual brand names and sizes, that would have been really useful so that I could have just chosen Henry J Weston then I would have known it was this brand so it was this percentage, because I think I definitely probably underestimated what it was.*

Nearly all of the participants mentioned that the apps did not provide reminders to enter drinks. As the majority of participants' drinking was done when out in pubs/bars/ clubs with friends, they reported that they simply forgot to enter the drinks throughout the night:

> *I used it every day but there wasn't any prompt or anything, so I tended to forget and then put it in the next day.*

Providing a well-designed graph to monitor alcohol consumption was also important to participants. It was suggested that the graph should provide additional information on well-being factors such as costs, mood, and the option to input important events such as birthdays to get a better understanding of their drinking:

> *Even if you put info you can kind of relate to why you drink more; sometimes like this money, you know, you just broke up with your boyfriend so it's really high and, you know, things like that. Or you've had loads of birthdays in that month so you keep going out, or you're celebrating finishing uni. Oh yeah, there could be a graph for financial...Yeah, that would scare me.*

Overall, what is demonstrated in the meaningfulness theme is that young adults feel that the current eSBI apps available to download do not provide the type of information or functionality of features, which are pertinent and targeted to the needs of young people.

Community

The second major theme was around the idea that to build a successful app, it must engage with the wider community of young people trying to cut down their drinking. Participants felt that in order to have the highest chance of success of reducing their drinking, it is paramount to have the support of other people around them:

> *I use a running app and it's a similar thing… when I run a race there was a lot of people that were in the group and we all kind of supported each other, so it's a similar thing and it motivates you to keep using it because you've got people on there that like what you do.*

As reflected in the meaningfulness theme discussed above, young people expressed the opinion that the most relevant aspects to them when considering cutting down on alcohol are broader lifestyle factors; young people want to be able to share these personal values via social media communities:

> *It's about making you feel better, rather than your alcohol use…that's where you link it into fitness and health and lifestyle because there's a massive Internet forum for that; people want to shout about that so I think if you link it into that more people will actually go on it and check what other people have done that is healthy today, rather than what have people been drinking today.*

In addition, participants wanted a personalized program of community support, which they could develop and manage themselves. This ranged from being able to set up goal-based groups with friends, to joining online groups that had similar goals to them:

> *You have everyone on there in the one community, everyone who joins is automatically in it, and you can talk to everyone who you want and your friends can join in, and if you want to create a group you can or if you want to add a group you can do what you do on Facebook and like send a message or send a request.*

However, it was equally important for participants to be able to manage this autonomously, having the option of creating individual goals, as well as joining groups of their choosing:

> *It depends how the individual uses it. Like if they want to join all these groups, then they can, and they can be a member of loads of things and talk to loads of people but if they don't want to do that and they just want their own personal profile and their own personal goals and just go on there to check how they're doing. Then they can do that so they don't feel pressured to spend hours on there.*

The participants made it clear that they wanted to be in control of the app, and this was reflected across the different themes. There were also strong opinions that anonymity and privacy relating to online safety were essential, in that users wanted to be able to control which personal information was made public. Being able to personalize and tailor every aspect, from choosing the type of information provided to them, setting up their own user profiles to selecting both their goals and the way they achieved them, whether alone or in a group were integral to a successful app.

Discussion

Principal Findings

The aim of this paper was to determine preferences for content, functionality, and visual appearance for an eSBI app to help harmful drinking young adults reduce their alcohol use. Phase 1 conducted a review of user feedback reviews on the iTunes App and Google Play stores, examining what users praised and criticized about eSBI apps, and recommendations for improvement. Phase 2 conducted a series of focus groups with young adults engaged in harmful drinking, exploring their views on current eSBI apps, and determined optimal features, appearance, and functionality to support them to reduce their drinking.

User App Review

The review generated three main findings. First, the element of eSBI apps that users praised most highly and most frequently was information and feedback. This suggests that good quality information and feedback is highly valued and desired by app users. Drinksmeter, which provides information and feedback on calories, costs, and their equivalents in unhealthy foods as well as normative feedback on alcohol consumption and a risk adjuster for mental health, received the highest number of this praise. This finding is consistent with the focus groups where Drinksmeter was also highly praised for its information and feedback. Future apps should pay close attention to the quality and type of information and feedback provided.

The second key finding was that users wanted a well-designed and easy-to-use drinks diary; all of the criticism for the drinks diary was for difficulty entering drinks, a finding that was also reflected in the focus groups. Monitoring of alcohol use is an important BCT to support reduction and is associated with greater effect sizes in SBI [20]. Future apps should include a range of data input options that allow users to enter drinks in the way that is easiest for them. Examples would be for users to be able to store their favorite drinks, be able to enter precise values for ABV and quantity, and have a broader selection of brands and types of drinks.

The third main finding was that what users disliked the most in terms of functionality was apps with software bugs. The most commonly criticized bug was for apps that crashed and froze. This is consistent with previous research; a study of over 250,000 reviews from the 20 most popular apps on the AppStore reported that functionality issues are the most criticized feature of an app, with app crashing being ranked number 3 of 12 [17]. An app that crashes often is likely to be deleted by the user before any engagement with the core objective, such as alcohol reduction, has occurred. App developers need to carefully test and improve the functionality of apps before releasing them for download or risk losing potential users in need.

Weaver et al [8] identified 44 alcohol reduction apps (in April 2012) and Crane et al [9] identified 91 alcohol reduction apps (in May 2014). Our study identified 201 apps (before exclusions) targeting alcohol monitoring and reduction. This would suggest that the alcohol app market has risen by 350% in 3 years. The current review did not examine adherence of apps to evidence-based guidelines, but as previous research reports, a large proportion of these apps are not evidence-based [8,9]. Apps endorsed and designed by health care and academic institutions are greatly needed.

Focus Groups

Analysis of the focus group data identified two main themes to consider when developing an app for young adults engaged in harmful drinking. First, all components of the app should be developed with the user in mind, so that the app is meaningful to the target group. In this study, young adults reviewed four apps that were not tailored to specific groups. The young adults unanimously agreed that this approach alienated them as younger users. They felt that the information provided was often meaningless as it did not take into account individual-level factors such as demographic characteristics, mental and physical health, as well as the drinking habits of young adults. Generic risk categories, advice, and recommendations for units were intangible to the participants, as they felt they did not consider in a realistic way how young adults drink. This finding is confirmed by another recently published qualitative study reporting that drinking guidelines lacked relevance and were felt to be unrealistic by adult drinkers [25]. In order to capture the attention of young adults, the risks and recommendations about drinking need to be presented in a manner that is relevant and meaningful to young adults; otherwise, such information is ignored. Future research needs to explore what these messages might look like.

On the other hand, what young adults wanted was information, goals, and guidance related to issues that were important to them. Participants' valued the positive benefits of not drinking such as maintaining one's physical appearance, being able to exercise more, saving money, not putting on weight, and limiting bad hangovers. These broader lifestyle and well-being factors, targeted at short-term health and image improvement, were most highly rated as providing motivation for drinking reduction. This was reflected in both the types of information and feedback young adults preferred, and the types of drinking goals they wanted to set for themselves. While some eSBI programs do touch on these factors, such as providing calorie feedback, the

current study shows how, for young adults, it needs to be at the core of the intervention for maximum impact.

This research is consistent with young adults' changing attitudes towards their health. A recent report suggests that one of the reasons for reductions in drinking over the last 10 years in 16-24 year olds in England is because young people have a greater awareness of the negative risks associated with drinking alcohol [26]. Equally, 60% of adults self-track their health data; such as weight, diet, or exercise routine [27], highlighting the importance of leading a technology-supported healthy lifestyle to the modern adult. These values were reflected in our study, suggesting that such lifestyle factors and their link to alcohol should be included in future eSBI apps.

The second major theme was that young adults wanted to be able to draw on the support of others to help them drink less. This was in relation to being able to give encouragement and motivation to other users, for example, through a feature similar to the Newsfeed on Facebook, as well as having the option to set up and join groups with their friends and the wider online community to achieve joint goals. This finding is consistent with previous research from other health care sectors. Both a study that designed a sexual health website [28] and another that designed an app for diabetes self-management in adolescents [29] reported how the target group wanted to be able to interact with and provide support to other users online.

Having a community support feature is a recognized BCT [30] that, when delivered via an app, is a component traditional face-to-face BI does not provide. Thus, it has the potential to improve the quality of the SBI intervention. Furthermore, wanting to have an app that has the capacity to engage with the larger network of online users is consistent with the popularity of social media apps, particularly among young adults [31]. Connecting online with other users is part of the fabric of day-to-day app and Web usage for young adults, and it is reasonable that any new apps should be designed with the target group's technology usage patterns in mind.

Limitations

This study has a number of limitations. There were surprisingly low numbers of reviews available for alcohol eSBI apps suggesting that generalizations beyond the current study should be taken with caution. As this is the only review of its kind in the alcohol field, the authors believe that the data are important, particularly as the results are confirmed by both previous research and the focus group data, and can be enhanced upon with future research. Furthermore, it was not possible to limit the user feedback reviews to young adults; therefore, the opinions expressed are not specifically targeted to this age group. This limitation was overcome by targeting Phase 2 only at young adults. Only the first 18 reviews for each app were selected to ensure the same number of reviews were coded across the four apps. Therefore, reviews of apps with more than 18 reviews were excluded. While this may have affected the direction of the results, the authors suggest that the reviews coded represent the most current version of the app, and therefore the most up-to-date reviews. Earlier reviews may have provided feedback on obsolete issues and content. It is also noted that as the app market is ever expanding and transforming, the apps reviewed represent a snapshot in time, and the opinions expressed may have already been subject to change.

Despite attempts to recruit a demographically representative sample, the focus groups included more female participants. This may have affected the direction of discussion and the development of key themes. The AUC app (a paid app) was excluded. This limited the range of apps reviewed, which may have excluded important feedback from the results. Approximately half of all participants who applied to join the study had a self-reported score of 16 or more on the AUDIT. This is higher than the prevalence rates of harmful drinking reported in previous research [32]. Participants potentially inflated their alcohol use to be able to enter the study, suggesting that the AUDIT scores are not representative of the sample's true drinking level. Conversely, due to self -selection bias, the sample may indeed have had higher drinking levels than the general population and therefore the preferences for content may reflect only the opinions of harmful drinkers with higher AUDIT scores. Additionally, only four focus groups were conducted with a total of 21 participants; however, the authors agreed that saturation was reached with the data and that the findings are transferable to other groups of young adults, particularly those living in London, who are studying or employed full or part-time. As a limitation to the study overall, aspects of esthetics of the apps were not discussed in detail, due to the nature of the topics that arose, and it is hard to draw any firm conclusions from the data on this aspect.

Conclusions

This paper has provided a unique contribution to the field of eSBI by determining, from a user perspective, preferences of young adults for app content and functionality. Good-quality, relevant, and targeted information is paramount, as are easy-to-use features and options to engage with the wider online community. It is hoped that this research will inform the development of future mHealth apps and increase the availability of evidence-based mHealth products on the market.

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Conflicts of Interest

None declared.

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Abbreviations

ABV: alcohol by volume
AUC: alcohol units calculator
AUDIT: Alcohol Use Disorder Identification Test
BAC: blood alcohol content
BCT: behavior change technique
C4L: Change for Life
eSBI: electronic screening and brief intervention
SBI: screening and brief intervention
UCD: user-centered design

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Original Paper

Impact of an mHealth Platform for Pregnancy on Nutrition and Lifestyle of the Reproductive Population: A Survey

Matthijs R Van Dijk[1], MD; Nicole A Huijgen[1], MD; Sten P Willemsen[2], MSc; Joop SE Laven[1], MD, PhD; Eric AP Steegers[1], MD, PhD; Régine PM Steegers-Theunissen[1], MD, PhD

[1]Erasmus Medical Center (MC), Department of Obstetrics and Gynecology, University Medical Center, Rotterdam, Netherlands

[2]Erasmus Medical Center (MC), Biostatistics, University Medical Center, Rotterdam, Netherlands

Corresponding Author:
Régine PM Steegers-Theunissen, MD, PhD
Erasmus Medical Center (MC)
Department of Obstetrics and Gynecology
University Medical Center
PO Box 2040
Rotterdam, 3000 CA
Netherlands
Phone: 31 107043598
Fax: 31 107036815
Email: r.steegers@erasmusmc.nl

Abstract

Background: Poor nutrition and lifestyle behaviors exert detrimental effects on reproduction and health during the life course. Therefore, lifestyle interventions during the periconceptional period can improve fertility, pregnancy outcome, and health of subsequent generations.

Objective: This survey investigates the compliance, usability, and initial effectiveness of the Web-based mHealth platform, Smarter Pregnancy.

Methods: A free subscription to the mHealth platform, Smarter Pregnancy, was provided to couples contemplating pregnancy (n=1275) or already pregnant (n=603). After baseline identification of inadequate nutrition and lifestyle behaviors, a personal online coaching program of 6 months was generated. Using multiple imputation and the generalized estimating equation model with independent correlations, we estimated the changes from inadequate to adequate nutrition and lifestyle behaviors over time. Subgroup analyses were performed for (1) overweight and obese women (body mass index [BMI] ≥25 kg/m^2), (2) pregnant women at the start of the program, and (3) couples.

Results: A 64.86% (1218/1878) compliance rate was observed and 54.7% (range 39.2-73.4%) of participants rated the program usability as positive or very positive. Adequate nutrition and lifestyle behaviors at baseline were 21.57% (405/1878) for vegetable intake, 52.61% (988/1878) for fruit intake, 85.44% (1303/1525) for folic acid use, 86.79% (1630/1878) for no tobacco use, and 64.43% (1210/1878) for no alcohol consumption. After 6 months of coaching, these lifestyle behaviors improved by 26.3% (95% CI 23.0-29.9) for vegetable intake, 38.4% (95% CI 34.5-42.5) for fruit intake, 56.3% (95% CI 48.8-63.6) for folic acid use, 35.1% (95% CI 29.1-41.6) for no tobacco use, and 41.9% (95% CI 35.2-48.9) for no alcohol consumption. The program showed the strongest effectiveness for participating couples.

Conclusions: This novel Web-based mHealth platform shows high compliance and usability, and users demonstrate improvements in nutrition and lifestyle behaviors. The next step will be further validation in randomized controlled trials and implementation.

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KEYWORDS

preconception care; nutrition; lifestyle; mHealth; pregnancy

Introduction

Worldwide, more than 45 million couples are contemplating pregnancy, of which around 22 million remain involuntarily childless. Moreover, of the more than 360 million pregnancies worldwide per year, at least 90 million end in miscarriage, 18 million result in congenital malformation, and 40 million result in children small for their gestational age. These reproductive and pregnancy failures largely originate in the periconceptional period, during which development and function of gametes, embryonic organs, and the placenta are programmed [1]. Poor periconceptional nutrition and lifestyle not only affect fertility and pregnancy outcome, but can also derange epigenetic programming with long-lasting health consequences [2]. Therefore, effective nutrition and lifestyle interventions in particular during this window of time will be an investment in healthy pregnancy and the health of current and future generations.

Currently, the most effective preconceptional interventions comprise weight loss, improvement of nutrition, use of folic acid supplements, and lowering the use of tobacco [3,4]. Unfortunately, women and men contemplating pregnancy or pregnant couples, as well as health care professionals, are often not aware of the detrimental effects of poor lifestyle behaviors [5-7]. These behaviors often accumulate not only in an individual, but also in couples, in particular among those with a low socioeconomic status, increasing the risk of a poor pregnancy outcome [8,9]. Therefore, it should be the responsibility of both health care professionals and patients to improve inadequate nutrition and lifestyle. To this aim, we previously developed and implemented a specific preconception outpatient clinic tailored to improve nutrition and lifestyle, which showed a 30% reduction of inadequate nutrition and lifestyle and a 65% increased chance of ongoing pregnancy after in vitro fertilization (IVF) treatment [6,10]. Obstacles of lifestyle counseling as part of periconceptional (clinical) care, however, require special expertise and time without reimbursement of costs.

Mobile health (mHealth) has the potential to transform health care delivery and to overcome obstacles by providing individual, tailored, and repeated information. Evidence is accumulating that mobile technology can effectively improve inadequate nutrition, lifestyle, and medication adherence [11]. Therefore, we developed the online, device-independent, Web-based coaching platform, *Smarter Pregnancy* [12]. This platform was based on scientific evidence of effective nutrition and lifestyle interventions, prevention and educational programs for noncommunicable diseases [13,14], and behavioral models, as well as our experience from the preconception outpatient clinic [6,15]. This mHealth platform aims to empower women, men, and health care professionals to improve inadequate nutrition and lifestyle. It also demonstrates the need for easily accessible, evidence-based interventions to improve the quality and effectiveness of periconceptional (clinical) care, the success of reproduction and pregnancy outcomes, as well as the prevention of disease during the life course [16,17].

Here we investigate the compliance, usability, and initial effectiveness of the Dutch version of this Web-based mHealth platform on changing inadequate nutrition and lifestyle behaviors in prepregnant women and their partners.

Methods

Study Population

In 2012 and 2013, women and men contemplating pregnancy or pregnant couples living in Rotterdam, the Netherlands, visiting the Erasmus Medical Center (MC), University Medical Center, or midwifery practices in Rotterdam, were recruited to the study. Recruits were invited to sign up for a free subscription to the Web-based Smarter Pregnancy platform [12]. This included 6 months of coaching on the most prevalent inadequate nutrition and lifestyle behaviors (ie, vegetable, fruit, and alcohol intake) or the most strongly demonstrated associations of behaviors with fertility and pregnancy course and outcome (ie, tobacco and folic acid supplement use).

Adequate daily intakes are defined as at least 200 grams of vegetables and at least two pieces of fruit, a folic acid supplement of 400 µg, and no tobacco or alcohol use [18]. Men were screened on the same behaviors, except for folic acid supplement use. Evaluation of the results of the baseline survey and the four follow-up screening surveys are shown on each participant's personal page as lifestyle risk scores in graphs and text, accompanied by personal advice according to preconceptional recommendations and Dutch guidelines [18]. If a participant completes the final screening survey at 6 months, we consider this as maximum compliance. More details are described in the next paragraph.

Smarter Pregnancy

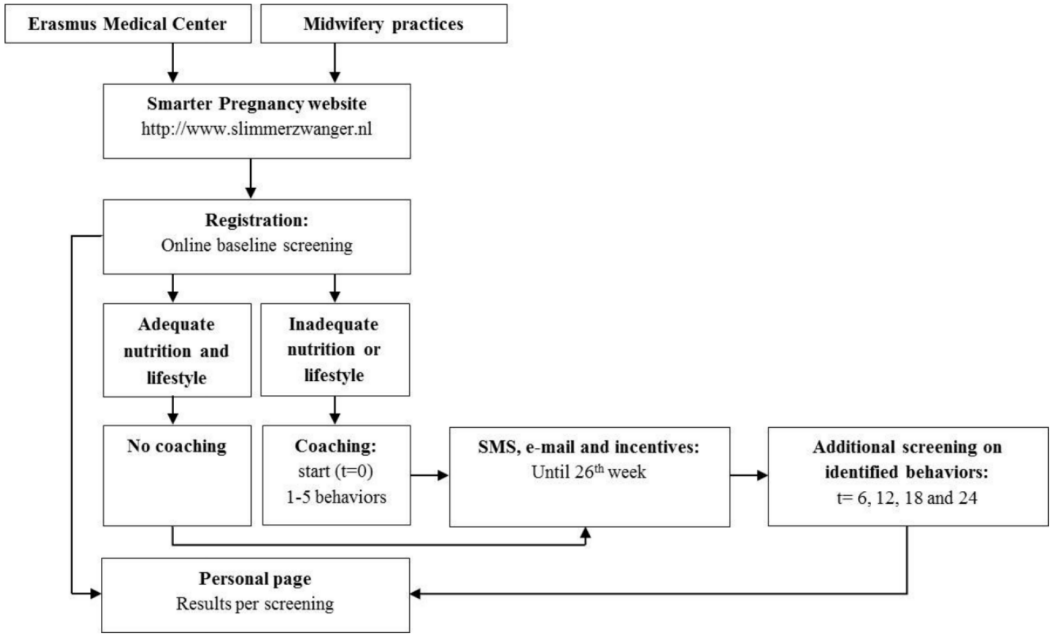
The coaching model developed for the Smarter Pregnancy platform is based on our research and expertise from the last 25 years on the impact of nutrition and lifestyle on reproduction as well as on pregnancy course and outcome [6,10,15,19,20]. In addition, we incorporated the following into the platform: results from the literature, Prochaska and Diclemente's transtheoretical model with a focus on the readiness for behavioral change, Bandura's social cognitive theory for self-efficacy, and Fogg's behavior model to include triggers to motivate and increase the ability to change [21-23]. Features of the attitude, social influence, and self-efficacy (ASE) model for coaching are applied; the ASE model has been frequently used for developing health education and prevention. Elements of this model comprise individual attitude, social influence, and self-efficacy aimed at the understanding and motives of people to engage in specific behavior [24].

The content of the individual coaching consisted of the baseline screening and follow-up screening at 6, 12, 18, and 24 weeks of the program. Coaching also included a maximum of three interventions per week comprised of short message service (SMS) text messaging and email messages containing tips, recommendations, vouchers, seasonal recipes, and additional questions addressing behavior, pregnancy status, body mass index (BMI), and adequacy of the diet. Every 6 weeks, participants were invited to complete a short, online, follow-up

screening survey to monitor the change in their inadequate nutrition and lifestyle behaviors. Results from the screening session compared to the previous screening sessions were shown on their personal page (see Figure 1). This page also provided access to additional modules (ie, applications) to support physical activity, an agenda to improve the compliance of hospital appointments and intake of medication, and a module to monitor the safety of prescribed medication. A summary of all individual results were available to be obtained at any point by the participant, and to be handed over or sent by email to the health care professional for further evaluation and support of preconceptional and antenatal care.

This mHealth platform complied with the highest rules of legislation for medical devices in Europe; therefore, it received the Conformité Européenne, classe 1 (CE-1), classification (2013) and can be used to improve the quality of medical care.

Figure 1. Overview of the Web-based Smarter Pregnancy program: registration, identification of inadequate nutrition and lifestyle behaviors, and coaching. SMS: short message service.



Statistical Analysis

We analyzed all participants who completed or prematurely resigned from the platform. Compliance was defined by the percentage of participants who completed the 6-month program. Usability was assessed using a digital evaluation form containing 26 questions whose answers were scored using a 4-point Likert scale; the ratings were *negative*, *neutral*, *positive*, and *very positive*. This was used to report on participants' satisfaction with the platform, which was subdivided into three categories: (1) design and interface, (2) content and coaching, and (3) perception and personal benefit. General characteristics and lifestyle behaviors were compared using chi-square tests for proportions, and *t* tests and Mann Whitney U tests for continuous variables.

Using a generalized estimating equation (GEE) model with an independent working correlation matrix, we modeled the fraction that scored *adequate* at each of the follow-up time points. In order to minimize selection bias, we used multiple imputation models to handle missing data of the participants who prematurely resigned. Therefore, a separate model was built for each of the five lifestyle behaviors of interest using all available information on each of the time points, as well as the subgroup indicators to impute the missing values. For each nutrition and lifestyle behavior, we examined those individuals that scored *inadequate* at baseline.

Subgroup analyses were performed between (1) normal weight and overweight or obese women defined as having a BMI of <25.0 and ≥25.0 kg/m^2, respectively, (2) nonpregnant and pregnant women at the start of the program, and (3) women-only participants and couples, who were defined as the woman and her male partner who followed his own personal coaching program at the same time, which was also dependent on pregnancy status. To create the area under the curve (AUC) of the linear predictor as an overall measure of effectiveness of the program, we calculated the average of the log odds ratio at the specific time points. For each subgroup, this average was compared with that of its complement (eg, obese versus nonobese, pregnant versus nonpregnant, and couples versus women without a participating male partner). SPSS version 21.0 (IBM Corp, Armonk, NY) software package was used and the level of significance was set to .05 for all analyses.

Ethical Approval

All data were anonymously processed. This survey was conducted according to the guidelines laid down in the

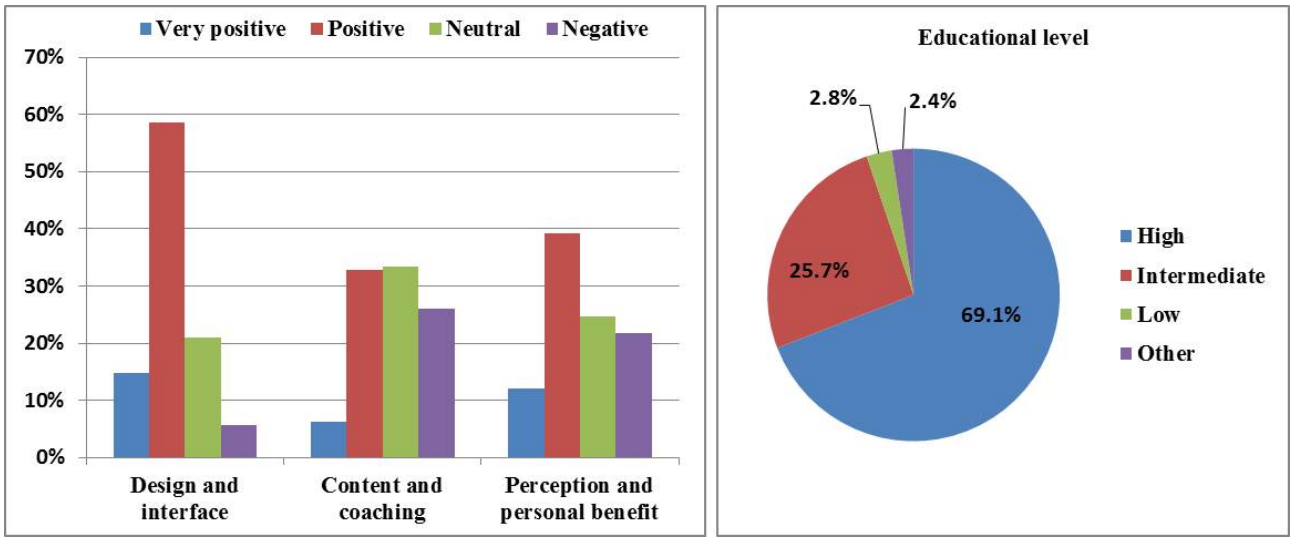
Declaration of Helsinki and all procedures involving patients were approved by the Medical Ethical and Institutional Review Board of the Erasmus MC, University Medical Center, Rotterdam, the Netherlands. Digital informed consent was obtained from all participants, allowing us to use the data for analysis.

Results

Compliance and Usability

Study compliance was 64.86% (1218/1878) among all participants who activated the program. Additional digital evaluation forms sent every 4 months to new participating women were received from 357 women out of 1878 (19.01%), of which 69.2% (247/357) were highly educated. The usability of the program was judged as *positive* or *very positive* by 54.7% of participants, and ranged from 39.2% (content and coaching) to 73.4% (design and interface) (see Figure 2).

Figure 2. Results of the evaluation of usability based on 357 evaluation forms. Usability of the Smarter Pregnancy program was subdivided into three program characteristics (left) and by participant educational levels (right).



Baseline Characteristics

We evaluated 1878 out of 2003 (93.76%) participants after exclusion of 125 (6.24%); these participants were excluded because of nonactivation due to incomplete registration or no data entry after subscribing to the application (see Figure 3). The baseline characteristics of the cohort (n=1878) who completed or prematurely resigned from the platform are depicted in Table 1. They are classified according to gender and further subdivided into groups that (1) completed the last screening and (2) resigned prematurely from the platform. No significant differences were observed in women and men that completed or resigned prematurely from the platform with regard to age, height, BMI, percentage of overweight and obesity, mean vegetable and fruit intake, percentage of inadequate folic acid supplement, and tobacco and alcohol use. The woman-to-man ratio of the participants was 4.3 to 1. Of the total group of 1525 registered women, 603 (39.54%) reported to be pregnant at baseline, of which 416 (69.0%) completed the program and 187 (31.0%) prematurely resigned (P =.04).

Table 1. Baseline characteristics of participants.

Baseline characteristics	Women (n=1525)			Men (n=353)		
	Completed (n=1003)	Stopped (n=522)	*P*	Completed (n=215)	Stopped (n=138)	*P*
General						
Age (years), median (IQR[a])	31.2 (27.7-34.6)	31.5 (27.9-35.2)	.81[b]	33.7 (30.1-37.0)	34.6 (30.4-38.1)	.64[b]
Height (cm), median (IQR)	169.0 (164.0-174.0)	170.0 (165.0-175.0)	.53[b]	183.0 (179.0-190.0)	185.0 (181.0-188.0)	.16[b]
Pregnant (yes), n (%)	416 (41.48)	187 (35.9)	.04[c]	N/A[d]	N/A	N/A
Body mass index (BMI) (kg/m^2)						
Total group BMI, median (IQR)	24.0 (21.3-27.6)	24.0 (21.7-27.0)	.53[b]	25.2 (23.7-27.8)	25.3 (23.2-27.5)	.30[b]
Overweight (BMI 25-29.99), median (IQR)	27.1 (25.8-28.4)	26.7 (25.9-28.1)	.25[b]	26.6 (25.5-28.1)	27.2 (25.9-28.2)	.48[b]
Overweight, n (%)	266 (26.52)	139 (26.7)		96 (44.7)	62 (45.0)	
Obese (BMI 30-60), median (IQR)	32.9 (31.3-35.8)	32.7 (31.2-36.1)	.52[b]	31.3 (30.8-35.1)	31.7 (30.3-35.1)	.42[b]
Obese, n (%)	141 (14.06)	68 (13.0)		22 (10.2)	10 (7.2)	
Nutrition						
Total group vegetable intake (g/day), median (IQR)	135.7 (96.4-185.7)	142.9 (100.0-185.7)	.90[b]	142.9 (100.0-192.9)	150.0 (107.1-185.7)	.88[b]
Inadequate vegetable intake (<200 g/day), n(%)	785 (78.27)	416 (79.9)	.23[c]	162 (75.3)	110 (79.7)	.19[c]
Total group fruit intake (pieces/day), median (IQR)	2.3 (1.3-3.4)	2.1 (1.3-3.3)	.32[e]	1.4 (0.7-2.3)	1.4 (0.5-2.2)	.46[e]
Inadequate fruit intake (<2 pieces/day), n (%)	427 (42.57)	232 (44.6)	.23[c]	139 (64.7)	92 (66.7)	.29[c]
Lifestyle						
Folic acid (no), n (%)	150 (14.96)	72 (13.8)	.59[c]	N/A	N/A	N/A
Smoking (yes), n (%)	119 (11.86)	54 (10.3)	.40[c]	48 (22.3)	27 (19.6)	.60[c]
Alcohol (yes), n (%)	258 (25.72)	165 (31.7)	.02[c]	151 (70.2)	94 (68.1)	.72[c]

[a]IQR: interquartile range.

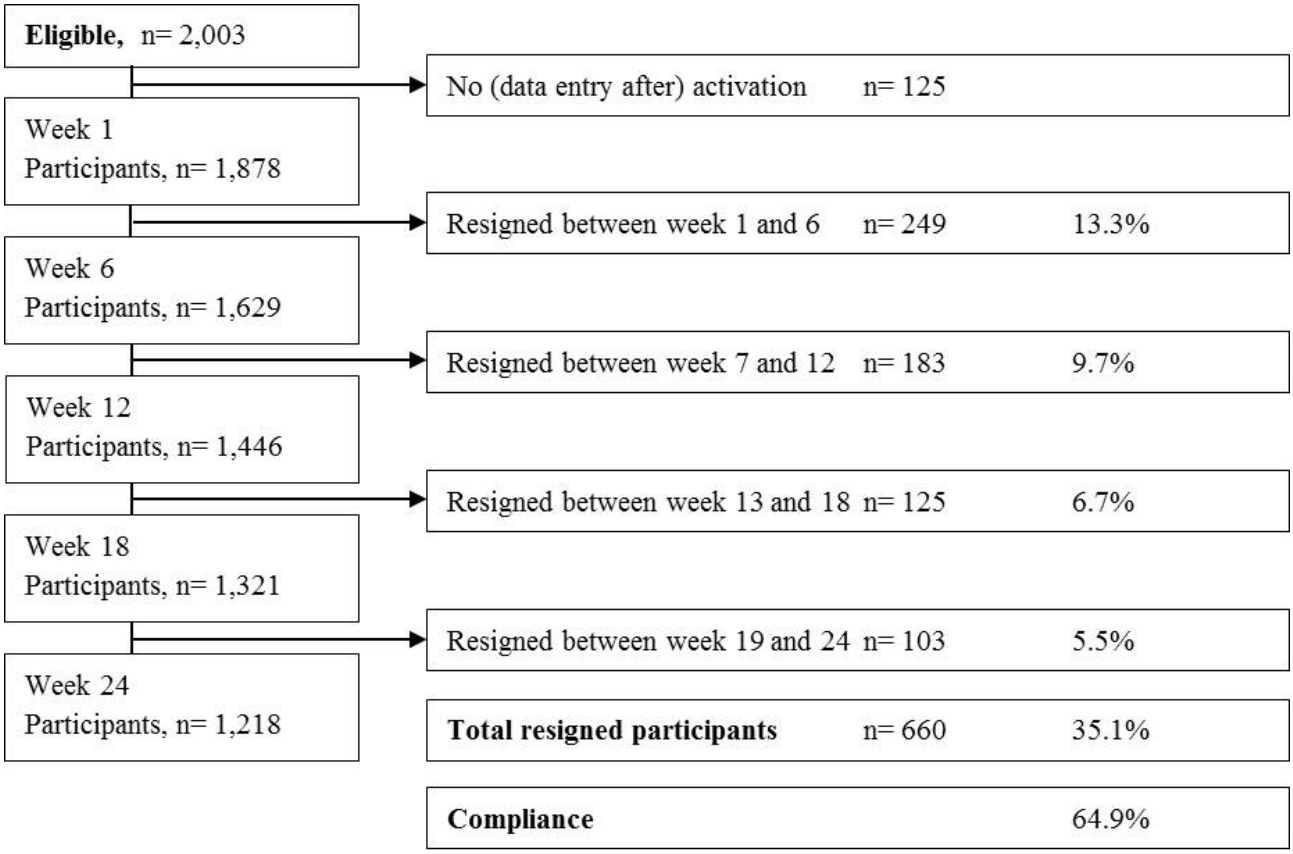
[b]Independent *t* test.

[c]Pearson chi-square test.

[d]N/A: not applicable.

[e]Mann Whitney U test.

Figure 3. Flowchart of the Smarter Pregnancy survey. Percentages are based on total participants (n=1878) in week 1.



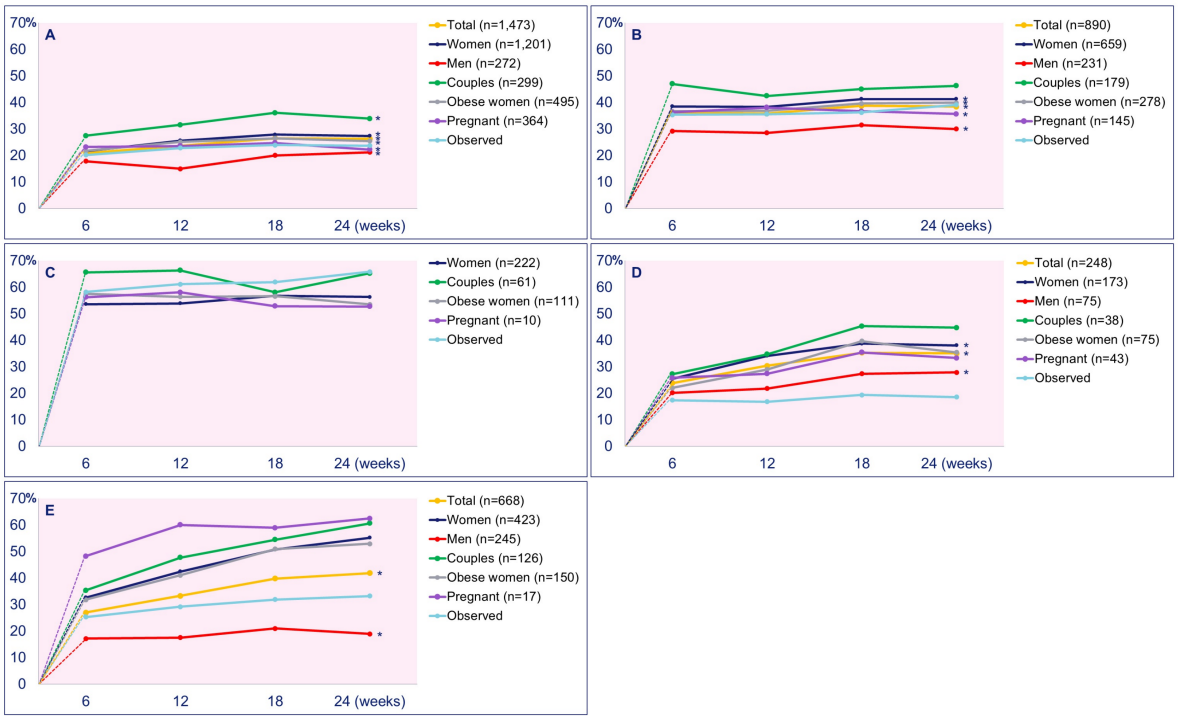
Baseline Nutrition and Lifestyle Behaviors

Adequate nutrition and lifestyle behaviors at baseline were 21.57% (405/1878) for vegetable intake, 52.61% (988/1878) for fruit intake, 85.44% (1303/1525) for folic acid use, 86.79% (1630/1878) for no tobacco use, and 64.43% (1210/1878) for no alcohol consumption. The most prevalent inadequate behavior among both women and men was vegetable intake, which was 78.75% (1201/1525) and 77.1% (272/353), respectively. Inadequate fruit intake was observed in 43.21% (659/1525) of the women and 65.4% (231/353) of the men, whereas only 14.56% (222/1525) of the women reported no folic acid supplement use. Tobacco use was reported for 11.34% (173/1525) and 21.2% (75/353) of the women and men, respectively. Alcohol consumption was reported in 27.73% (423/1525) of all women and 69.4% (245/353) of all men. Women who resigned from the platform prematurely showed a significantly higher percentage of alcohol consumption of 31.6% (165/522) versus 25.72% (258/1003) (P =.02).

Effectiveness

Figure 4 depicts the changes in nutrition and lifestyle behaviors of the total and specific subgroups. Results at every follow-up screening point have been compared to baseline values. At baseline, vegetable intake was inadequate in 1473 out of 1878 participants (78.43%). An improvement of 20.9% (95% CI 18.5-23.5) was observed after 6 weeks and persisted to an increase up to 26.3% (95% CI 23.0-29.9) at 6 months (see Figure 4 , A). Inadequate fruit intake was observed in 890 out of 1878 participants (47.39%) at baseline and improved by 36.1% (95% CI 33.0-39.3) and 38.4% (95% CI 34.5-42.5) at 6 weeks and 6 months, respectively (see Figure 4 , B). The figures for inadequate folic acid supplement use observed in 222 out of 1525 women (14.56%) showed a decrease of 53.6% (95% CI 46.8-60.3) and 56.3% (95% CI 48.8-63.6) at 6 weeks and 6 months, respectively (Figure 4 , C). At baseline, the prevalence of tobacco and alcohol use was 248 out of 1878 (13.21%) and 668 out of 1878 (35.57%), respectively. Tobacco and alcohol use were further reduced by 23.8% (95% CI 16.8-32.6) and 27.0% (95% CI 22.4-32.1) at 6 weeks and 35.1% (95% CI 29.1-41.6) and 41.9% (95% CI 35.2-48.9) at 6 months, respectively (Figure 4 , D and E). All percentages are depicted in Multimedia Appendix 1.

Figure 4. Vegetable intake (A), fruit intake (B), folic acid use (C), tobacco use (D), and alcohol consumption (E) by participants. Improvement of behavior from inadequate at baseline to adequate at every screening point is shown as the percentage (y-axis) of the total group or subgroup. The dotted lines representing the change in relation to baseline are included to improve the interpretation of the graphs. *P<.05 at all screening points. All percentages (per screening point) and areas under the curve, including P values, are included in Multimedia Appendix 1.



Subgroup: Overweight and Obese Women

Baseline screening revealed 614 out of 1525 (40.26%) and 190 out of 353 (53.8%) overweight and obese women and men, respectively. Subgroup analysis showed patterns of inadequate nutrition and lifestyle behaviors in these women and men comparable to the total group (see Figure 4). The AUCs of the five inadequate lifestyle behaviors were comparable in overweight and obese (BMI ≥25 kg/m^2) and nonobese (BMI <25 kg/m^2) women and men (see Multimedia Appendix 1).

Subgroup: Women Pregnant at Entry

A trend of comparable improvement of vegetable, fruit, and folic acid intake was shown in pregnant and nonpregnant women. Cessation of tobacco and alcohol use was higher in pregnant women although the groups were small (n=10 and n=17, respectively). The AUCs did not differ significantly (see Multimedia Appendix 1).

Subgroup: Couples

A total of 353 couples were coached, of which 215 (60.9%) completed the 6 months of coaching. The program was most effective on changing inadequate nutrition and lifestyle behaviors, except for tobacco use, when both the women and men used the program compared to the group of women only (see Figure 4).

Discussion

Smarter Pregnancy is the first CE-1-certified, Web-based, personal mHealth platform tailored to convert inadequate to adequate nutrition and lifestyle behaviors in couples during the prepregnancy and pregnancy periods. This survey highlights the very high prevalence of inadequate intake of vegetables, fruit, and folic acid supplements, as well as tobacco and alcohol use in both women and men in the prepregnancy and pregnancy periods. Previous research by Hammiche et al and Vujkovic et al targeting the same period showed comparable results for inadequate vegetable and fruit intake (32.7-80.6%), inadequate folic acid supplement use (18.9-37.9%), tobacco use (11.3-31.0%), and alcohol use (35.5-66.0%) [6,25]. Screening tools and programs, such as *ZwangerWijzer* [26] and *Healthy Pregnancy 4 All*, have been developed and are being implemented [27,28]. However, routine preconceptional care is still only scarcely available. There is some evidence from other groups substantiating that eHealth and mHealth can support and enhance preventive preconceptional health care interventions.

The strengths of this survey are the high number of participants (n=1878), the high compliance of 64.86% (1218/1878) of participants to complete the 6 months of coaching, the positive feedback of the usability, participation of couples, and the analysis in which selection bias was limited by multiple imputation. The high appreciation of usability and initial effectiveness of this program on improving lifestyle behaviors suggests increased awareness and strong adherence to the given

insights and recommendations. A possible explanation for these results is the multifunctional, interactive, and individual character of the coaching, which is distinctive compared to most eHealth and mHealth tools providing information only without taking individual conditions into account. Other strengths are the prospective and automatic data collection, as well as the subgroup analyses addressing the influence of pregnancy status, overweight and obesity, gender, and the participation of individuals or couples.

Our previous research has shown that a short self-administered risk score is a valid method to identify adequate or inadequate vegetable and fruit intake on both food group and nutrient levels [15]. Moreover, the percentages of these inadequate nutrition and lifestyle behaviors are in line with our data from the preconceptional outpatient clinic [6,10]. Limitations of this survey are the absence of validation by biomarkers and, inherent to the design of a survey, the absence of a control group. Moreover, using the Internet and a website in the Dutch language excludes groups using other languages and those having less access to the Internet.

In general, the endless opportunities of mHealth tools and knowing how to access them can be of unprecedented importance, especially with regard to health care. The rise of mobile technology by mobile phones, with more than one billion users worldwide, and other handheld devices also contributes to accessibility regarding online information and recommendations concerning healthy nutrition and lifestyle behaviors during the preconceptional period [29,30]. Couples contemplating pregnancy are often unaware of the availability and importance of these recommendations [5,6,19,31]. Unfortunately, health care professionals are often unfamiliar with up-to-date, evidence-based preconception care; it should be their responsibility to educate and increase patient awareness concerning healthy lifestyle behaviors in order to improve their chances to conceive and ensure a healthy prenatal environment for all couples [5]. Our findings contribute to previous research suggesting that both women and men should be involved in preconceptional care [32]. We demonstrated that the support of the partner by utilizing the same platform increases the effect of this intervention.

It is known that changing inadequate nutrition and lifestyle behaviors and maintaining healthy behavior is hard to accomplish, especially when there is a possibility that the goal to become pregnant will not be reached. Currently, only a small group of women that will not conceive spontaneously and those with a previous complicated pregnancy may receive preconceptional counseling by a health care professional (eg, general practitioner or gynecologist). Because the Smarter Pregnancy program has the potential as an mHealth platform to reach and educate a much larger population, including men, its use and implementation in health care is of interest to patients, health care professionals, and health care insurance companies to reduce health care costs in the future. The initial results of this survey were encouraging; this opens up the opportunity of implementation and conducting randomized controlled trials to further substantiate the findings on changing nutrition and lifestyle behaviors, and to further demonstrate the clinical effectiveness and cost-effectiveness of this mHealth platform in several target groups.

In conclusion, Smarter Pregnancy is a mHealth Web-based coaching platform that has the potential to improve and maintain healthy nutrition and lifestyle behaviors in women as well as men and, in particular, couples in the prepregnancy and pregnancy periods. These findings are important for further improvement of the quality and accessibility of preconceptional and pregnancy care, fertility, pregnancy course and outcome, and ultimately health from the earliest moment and throughout the life course.

Acknowledgments

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Authors' Contributions

MRvD acquired, analyzed, and interpreted data and drafted the manuscript. NAH acquired data and critically reviewed the manuscript. SPW analyzed and interpreted data and critically reviewed the manuscript. JSEL was responsible for reproductive patient care and EAPS for preconceptional and antenatal patient care; they both critically revised the manuscript for intellectual content. RPMST initiated and developed the Smarter Pregnancy platform and was responsible for all aspects of the study, including drafting of the manuscript, interpretation of data, and contributing to all critical revisions of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Data are presented per risk factor per screening point as the percentage of improvement from inadequate to adequate behavior of the total group or subgroup, including the 95% confidence interval. Area under the curve (AUC) is presented as log odds ratio: AUC subgroup versus AUC complement, difference, and corresponding P value.

[PDF File (Adobe PDF File), 108KB - mhealth_v4i2e53_app1.pdf]

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Abbreviations

ASE: attitude, social influence, and self-efficacy
AUC: area under the curve
BMI: body mass index
CE-1: Conformité Européenne, classe 1
GEE: generalized estimating equation
IQR: interquartile range
IVF: in vitro fertilization
MC: Medical Center
mHealth: mobile health
Mrace: Medical Research Advisory Committee
N/A: not applicable
SAG: Stichting Achmea Gezondheidszorg
SMS: short message service

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Original Paper

Mobile Phone Apps for Preventing Cancer Through Educational and Behavioral Interventions: State of the Art and Remaining Challenges

Steven Coughlin[1*], PhD; Herpreet Thind[1*], MBBS, PhD, MPH; Benyuan Liu[2*], PhD; Nicole Champagne[1], EdD; Molly Jacobs[3], MPH; Rachael I Massey[4], MSc, MPA

[1]University of Massachusetts Lowell, Department of Community Health and Sustainability, Lowell, MA, United States

[2]University of Massachusetts Lowell, Department of Computer Science, Lowell, MA, United States

[3]Lowell Center for Sustainable Production, Lowell, MA, United States

[4]Toxics Use Reduction Institute, Lowell, MA, United States

[*]these authors contributed equally

Corresponding Author:
Steven Coughlin, PhD
University of Massachusetts Lowell
Department of Community Health and Sustainability
One University Avenue
Kitson Hall 313A
Lowell, MA, 01854
United States
Phone: 1 404 983 2524
Fax: 1 978 934 2040
Email: stevecatlanta@aol.com

Abstract

Background: Rapid developments in technology have encouraged the use of mobile phones in smoking cessation, promoting healthy diet, nutrition, and physical activity, sun safety, and cancer screening. Although many apps relating to the prevention of cancer and other chronic diseases are available from major mobile phone platforms, relatively few have been tested in research studies to determine their efficacy.

Objective: In this paper, we discuss issues related to the development and testing of new apps for preventing cancer through smoking cessation, sun safety, and other healthy behaviors, including key methodologic issues and outstanding challenges.

Methods: An exploratory literature review was conducted using bibliographic searches in PubMed and CINAHL with relevant search terms (eg, smartphones, smoking cessation, cancer prevention, cancer screening, and carcinogens) to identify papers published in English through October 2015.

Results: Only 4 randomized controlled trials of the use of mobile phone apps for smoking cessation and 2 trials of apps for sun safety were identified, indicating that it is premature to conduct a systematic search and meta-analysis of the published literature on this topic.

Conclusions: Future studies should utilize randomized controlled trial research designs, larger sample sizes, and longer study periods to better establish the cancer prevention and control capabilities of mobile phone apps. In developing new and refined apps for cancer prevention and control, both health literacy and eHealth literacy should be taken into account. There is a need for culturally appropriate, tailored health messages to increase knowledge and awareness of health behaviors such as smoking cessation, cancer screening, and sun safety. Mobile phone apps are likely to be a useful and low-cost intervention for preventing cancer through behavioral changes.

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KEYWORDS

mobile phone apps; cancer; early detection of cancer; diet; environmental carcinogens; health literacy; nutrition; obesity; prevention; randomized controlled trials; screening; smoking; sun safety; weight loss

Introduction

There has been increasing interest in the use of mobile phone apps to promote smoking cessation, healthy eating, physical activity, and other behaviors associated with reduced risk of cancer morbidity and mortality [1-6]. Mobile phone apps have lowered costs, reduced the burden to participants, and overcome some limitations of traditional in-person behavioral weight loss programs [4-6]. Established interventions for smoking cessation and weight loss are resource-intensive, a factor that poses barriers for full participation and widespread dissemination. Mobile phone apps provide a useful and low-cost way to disseminate cancer prevention and control information to the general population and to particular at-risk populations [4].

Rapid technological advances have led to the emergence of smartphones that combine the voice and text messaging functions of mobile phones with powerful computing technologies that can support third-party apps, access to the Internet, and wireless connectivity with other devices [7]. The boom in mobile health (mHealth) has been made possible by the high penetration of Internet access, lower-cost access to broadband Internet, improvement of morbid supporting services, and increased use of smartphones [8]. About 58% of adults in the United States owned a smartphone in 2013 and the percentage is projected to surpass 90% by 2020 [8,9]. About 64% of African Americans, 60% of Hispanics, and 53% of Caucasians in the United States owned a smartphone [10]. In addition to seeking health information, people use health apps to monitor their own health conditions and to manage their health [8]. For example, 38% of health app users use an app to track their exercise [11].

A mobile app is a computer program designed to run on smartphones or other mobile devices. All major smartphone platforms provide third-party developers with app programming interfaces that can be used to build special purpose apps referred to as native apps [7]. Smartphone apps can have a variety of features including visually engaging design, video and audio capabilities, unrestricted text capabilities, access without cellular or Internet connection, optimized smartphone screen size, content sharing via social media, and tracking progress anywhere and anytime [12]. In April 2012, there were an estimated 13,600 consumer health apps for the iPhone. The rapid increase in mobile apps has led to the proliferation of blogs, magazines, and dedicated online app-discovery services [13].

A variety of apps relating to cancer prevention, smoking cessation, diet, nutrition, and weight control are available from major smartphone platforms such as iPhone, Android, Nokia, and BlackBerry. Common behavioral change techniques include providing feedback, goal-setting, self-monitoring, and planning social support and change [14]. However, relatively few have been tested in randomized controlled trials to determine their efficacy in promoting health [7,15]. In addition, few of these apps are based on theories of health behavior change, most do not include evidence-based features, such as reinforcement, and existing apps often do not provide evidence-based recommendations for cancer prevention [1,7,15,16]. Furthermore, few studies have examined the general cognitive motivators that prompt people's use of health apps [8].

In this viewpoint, we discuss issues related to the development and testing of new apps for preventing cancer through smoking cessation, healthy diet and nutrition, physical activity, weight management, cancer screening, and sun safety, including key methodologic issues and outstanding challenges related to methodology, design issues, and regulatory issues. In an exploratory literature review intended to inform our commentary, we review published studies on the acceptability and effectiveness of mobile phone apps designed to promote behaviors that reduce risk of cancer [17,18].

Of particular interest were randomized control trials of the effectiveness of mobile phone apps to promote healthy behaviors such as smoking cessation and sun safety. Although mobile health apps related to telemedicine, cancer diagnosis and treatment, and oncology clinical trials also hold promise for cancer prevention and control [19-21], the focus of this review is on mobile phone apps for promoting healthy behaviors and cancer risk reduction through educational and behavioral interventions. As there have been recent reviews of the use of mobile phone apps to promote healthy diet, nutrition, and physical activity [5,6], we narrowed the focus of our exploratory literature review to randomized controlled trials of the use of mobile phone apps for smoking cessation, cancer prevention, cancer screening, or avoiding carcinogens.

Methods

We conducted bibliographic searches in PubMed and CINAHL with relevant search terms: (smartphones) and ((smoking cessation) or (cancer prevention) or (cancer screening) or (carcinogens)). Papers published in English through October 2015 were identified using relevant MeSH search terms and Boolean algebra commands. The searches were not limited to words appearing in the title of a paper. Studies that did not have a randomized controlled or pre-post test design were excluded along with those that focused on patients with cancer or other chronic diseases (ie, mobile phone apps for disease management). Randomized controlled trials are the most rigorous study design and the standard for most of the cancer prevention and control interventions (eg, cancer screening). Information obtained from bibliographic searches (title and topic of paper, information in abstract, geographic locality of a study, and key words) was used to determine whether to retain each paper identified in this way. We also looked for relevant papers published in *JMIR mHealth and uHealth* and *JMIR Cancer*. In addition, we identified reports included in Cochrane reviews [22] and reviewed the references of published review articles. More general searches were conducted that focused on eHealth literacy and methodologic issues in the development of mobile health apps.

Results

A total of 220 papers were identified in the bibliographic searches (Figure 1). By screening abstracts or full-text articles, 4 randomized controlled trials of the use of mobile phone apps

for smoking cessation were identified (Table 1). Valdivieso-Lopez et al [23] designed a cluster randomized controlled trial of a mobile phone app for smoking cessation in primary care centers in Catalonia, Spain. The efficacy of the mobile phone app combined with clinical practice guidelines for smoking cessation will be compared with clinical practice guidelines alone. The participants in the 6-month intervention trial will be smokers who have 10 or more cigarettes per day, aged 18-30 years, who are motivated to quit smoking. The outcome measure will be abstinence at 12 months confirmed by exhaled air carbon monoxide concentration. The app is being designed as a serious game that offers users the opportunity to develop skills and strategies for smoking cessation while trying to achieve the game's objectives. Results from the trial have not been published.

Table 1. Randomized controlled trials of mobile phone apps for promoting smoking cessation.

Study	Sample	Design	Results	Other information
Valdivieso-Lopez et al (2012)	Smokers of 10 or more cigarettes per day, aged 18-30 years who are motivated to quit smoking, seen in primary care centers in Catalonia, Spain	Cluster randomized controlled trial of a mobile phone app for smoking cessation combined with clinical practice guidelines, compared with clinical practice guidelines alone. The outcome measure will be abstinence at 12 months confirmed by exhaled air carbon monoxide concentration	Not yet available	The app is being designed as a serious game which offers users the opportunity to develop skills and strategies for smoking cessation while trying to achieve the game's objectives
Buller et al. (2014)	102 US smokers aged 18 to 30 years	Randomized controlled trial of a mobile app compared with text messaging (12-week pretest-posttest trial). Self-reported usability of the mobile phone app and quitting behavior (quit attempts, point prevalence, 30-day point prevalence, and continued abstinence) were assessed in posttests	A sizeable percentage of smokers reported being abstinent at 12-weeks (66% of smokers who completed the intervention trial, 44% of all smokers). Those in the text messaging group were more likely to be abstinent than those in the mobile phone app group (P <.05)	
Bricker et al 2014	196 adults who smoked at least five cigarettes per day for at least past 12 months, and were motivated to quit and interested to learn skills to quit smoking	Double-blind, randomized controlled trial of the effectiveness of a mobile phone delivered app (QuitGuide) versus the National Cancer Institute's SmartQuit app for smoking cessation. The outcome measure was self-reported 30-day point prevalence of abstinence (ie, no smoking in the last 30 days).	The overall quit rates were 13% in SmartQuit versus 8% in QuitGuide (odds ratio=2.7, 95% confidence interval 0.8-10.3)	
Baskerville et al. 2015	1354 smokers in Canada, aged 19-29 years	6-month, randomized controlled trial of a mobile phone app (Crush the Crave) versus an evidence-based self-help guide. The primary outcome will be self-reported, 30-day point prevalence of abstinence	Not yet available	

Buller et al [24] conducted a randomized controlled trial of a mobile app compared with text messaging to support smoking cessation. A total of 102 smokers aged 18 to 30 years participated in the 12-week, pretest-posttest trial. Self-reported usability of the mobile phone app and quitting behavior (quit attempts, point prevalence of abstinence, 30-day point prevalence, and continued abstinence) were assessed in posttests. A sizeable percentage of smokers reported being abstinent at 12-weeks (66% of smokers who completed the intervention trial, 44% of all smokers). Those in the text messaging group were more likely to be abstinent than those in the mobile phone app group (P <.05).

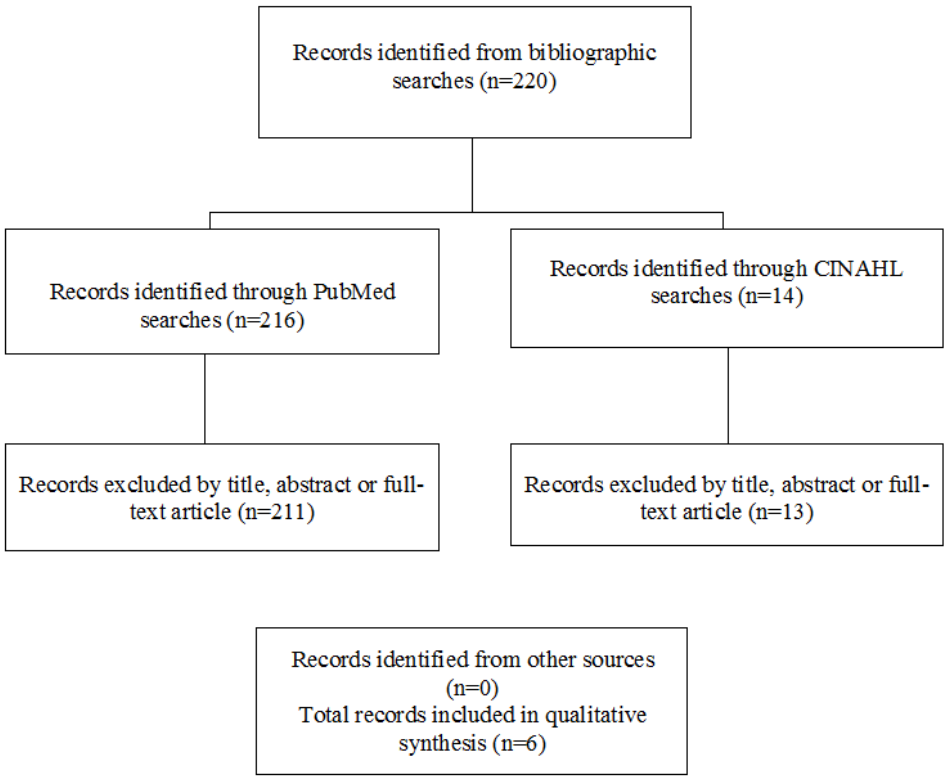
Bricker et al [8] conducted a double-blind, randomized controlled trial to examine the efficacy of a mobile phone-delivered app (QuitGuide) based upon the acceptance and commitment therapy (ACT) model of behavioral change, compared with the National Cancer Institute's SmartQuit app for smoking cessation. The latter is based on US Clinical Practice Guidelines. A total of 196 adults, who smoked at least 5 cigarettes per day for at least past 12 months and were motivated to quit and interested to learn skills to quit smoking, participated in the trial. The outcome measure was 30-day point prevalence abstinence (ie, no smoking in the past 30 days). The

overall quit rates were 13% in SmartQuit versus 8% in QuitGuide (odds ratio=2.7, 95% confidence interval 0.8-10.3).

Baskerville et al [25] is conducting a 6-month, randomized controlled trial of the efficacy of a mobile phone app (Crush the Crave) compared with an evidence-based self-help guide. A total of 1354 smokers in Canada, aged 19-29 years, will be randomized to the trial. The primary outcome is self-reported, 30-day point prevalence of abstinence. Results from the trial have not yet been reported.

Only two trials of the use of mobile phone apps for promoting sun safety were identified [9,26]. Our bibliographic search did not identify any published randomized controlled trials of the use of mobile phone apps to promote breast or colorectal cancer screening. In addition, there were no published studies regarding the use of apps to help people avoid carcinogenic exposures in work and home environments.

Figure 1. Summary of search and exclusion process for identified randomized controlled trials.



Discussion

Bender et al [7] examined the purpose and content of cancer-related mobile phone apps available for use by the general public and the evidence for their utility and effectiveness. They systematically reviewed the official stores for the four major mobile phone platforms (iPhone, Android, Nokia, and BlackBerry). Apps were included in their review if they focused on cancer and were available for public use. In addition, they systematically reviewed the literature using MEDLINE, Embase, and the Cochrane Library to identify evaluations of cancer-related mobile phone apps. A total of 295 apps from mobile phone app stores met their inclusion criteria. The reported app purpose was to raise awareness about cancer (32.2%, 95 of 295), to provide educational information about cancer (26.4%, 78 of 295), assist in early detection (11.5%, 34 of 295), and cancer prevention (2.0%, 6 of 295). Their review of the health literature identified 594 papers, but none was deemed eligible as they did not report an evaluation of a cancer-focused mobile phone app [7]. In addition, 17 apps focused on the early detection of breast cancer. Many of the apps promoted a charitable organization or supported fund-raising efforts. The authors noted several concerns including the lack of evidence of app effectiveness or description of the procedures or data sources (eg, evidence, theory) and discrepancies between information generated on mobile phone apps and evidence-based guidelines [7]. Mobasheri et al [15] reviewed major app stores (Apple iTunes, Google Play, BlackBerry World, and Windows Phone) using breast symptoms and diseases. A total of 185 breast apps were identified, of which 139 (75.1%) focused on breast cancer. Most of the apps were educational (n =94) or self-assessment tools (n =30). Few of the apps were evidence-based (14.2%) or involved medical professionals in their development (12.8%). Potential patient safety concerns were identified in 29 (15.7%) apps [15]. In March 2014, Bricker et al [12] identified 546 smoking cessation apps in the Apple Store and Google Play that were downloaded

to mobile phones an estimated 3.2 million times in the United States and 20 million times worldwide.

The number of randomized controlled trials of the efficacy of mobile phone apps in smoking cessation and sun safety is still modest [9,26]. Differences in study design (eg, choice of a comparison group, outcome measures, and sample size) and mobile phone app functionalities also increase the difficulty of drawing firm conclusions about the effectiveness of apps in promoting behaviors associated with reduced cancer risk. Nevertheless, mobile phone apps can be efficacious in promoting smoking cessation and are likely to be a useful and low-cost intervention for smoking cessation in the general population.

Design Issues

Mobile apps, such as those used for cancer prevention and control, are developed using emulators in specialized development environments. The development of apps must take into account the wide variety of screen sizes, hardware specifications, and configurations of mobile devices, as well as the need to run on a battery. In order to have an understandable and user-friendly interface, mobile user interface design takes into account display screens and input. The interface of users with their device includes both hardware and software components. Constraints considered by mobile user interface design include the limited attention of users and the device's screen size in relation to a user's hand.

Guidelines for developing mobile apps are available from academic and industry sources [27-29]. To help ensure the development of a successful app, guidelines for the development of mobile apps highlight the need for an initial analysis of requirements (understand the basic requirements for a proposed app), technology and strategic planning (find the best technology based on the requirements and to strategically plan a project), design and architecture (identify a suitable design, architecture, and interface for the mobile app), development and coding (begin coding modules while keeping the design in mind), testing and approval (test the app on a live server to identify and fix any coding bugs), and implementation [28].

Once developed, prototype apps are subjected to heuristic evaluation and field-testing. Evidence-based heuristics have been developed for evaluating the demands that mobile apps make on users, in terms of health literacy and usability, that is, the extent to which the app is practical and convenient for users [30]. The evaluations identify ways the design of the app could be helpful or detrimental to users with limited eHealth or computer literacy [30]. Heuristics recommended by Monkman et al [30] include:

1. Immediately inform users of purpose and engage users (identify the purpose and audience on the home screen)

2. Use complementary interaction methods (make use of alternative inputs such as touch screen and voice commands) and outputs (eg, audio recordings, videos, and graphics)

3. Leverage interactivity (offer interactive tools such as glossaries, tutorials, and quizzes to engage users with the information and to provide performance feedback)

4. Provide accurate, colloquial, comprehensive, succinct content (written information should be brief, relevant, and in users' vernacular)

5. Provide tailored, flexible, and layered content (prioritize information according to importance, provide succinct summaries, allow users to access more detailed information, offer content in multiple languages)

6. Use visuals to complement text but avoid tables (visuals such as pictures, videos may enhance written information)

7. Use simplistic consistent navigation (keep users oriented, use linear navigation to facilitate forward and backward movement, use large buttons and clearly labeled links, and provide a search engine)

8. Use simplistic, consistent displays (avoid on screen complexity and the need for scrolling by limiting information on each page or screen).

Simplicity and ease of use are often desirable. For example, if health apps require users to complete multiple steps in order to access information (eg, requiring them to provide numerous details about their meals in order to obtain information about their daily caloric intake), the complex and repetitive process requires users to expend a great deal of their time and mental energy, which can negatively impact their willingness to use the app [14]. It is helpful to complement text information with visuals and to engage users by offering interactive learning tools and resources. To improve readability, low contrast or distracting colors (eg, shadows) should be avoided in an app.

Depending on the app that is being evaluated, it may also be helpful to: (1) provide clear and comprehensive communication of risks (describe risks in ways that users will understand and avoid logarithmic scales); (2) provide clear depiction of monitoring data (facilitate pattern recognition and emphasize values outside of acceptable range); and (3) allow users to adjust the display size using familiar input (eg, pinch to zoom, use appropriately sized interface elements, and limit the amount of information displayed) [30]. Heuristic evaluations provide rapid, low-cost assessments that can help to improve the usability of an app, before conducting more expensive and time-consuming usability testing with samples of users [30].

Design Challenges

One challenge for the development of mobile phone apps for cancer prevention is that people may be more likely to use an app for a regular behavior such as healthy eating, physical activity, or weight management than an app that focuses on behaviors such as cancer screening that are only required every 5-10 years or biannually. It may be helpful to address multiple cancer prevention behaviors (eg, healthy diet, nutrition, physical activity, and avoidance of known or suspected carcinogens in home or work environments) in the same app [31]. A further issues is that cancer prevention apps that are less popular in the general population could be useful tools for people at increased risk due to a personal or family history of cancer or if recommended by physician (eg, as an adjunct to a smoking cessation program in primary care).

For mobile apps to be useful for preventing and controlling cancer in diverse populations, they must be suitable for people with varying levels of health literacy, eHealth literacy, computer literacy, and scientific literacy. The Institute of Medicine defined health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" [32]. Health literacy is comprises numerical literacy (numeracy), print literacy, and cultural and conceptual knowledge [32]. On average, people with low health literacy have poorer overall health status, inefficient use of health care services, poor patient-provider communication, and higher risk of premature mortality, compared with people with higher health literacy [32-34]. Although few published studies have examined the health literacy levels of educational information provided via mobile apps, in other media, cancer prevention and control messages are often written at too high a reading level for individuals with marginal literacy skills [35]. Health literacy instruments that have been assessed for validity and feasibility as screening tools in clinical settings and in research include, the Test of Functional Health Literacy in Adults (TOFHLA), the Shortened Test of Functional Health Literacy in Adults (S-TOFHLA), the Rapid Estimate of Adult Literacy in Medicine (REALM), and the Shortened Rapid Estimate of Adult Literacy in Medicine (REALM–R) [36-39]. A computer-based version of TOFHLA has been pilot tested [40].

In contrast to the more general concept of health literacy, eHealth literacy is "the ability to seek, find, understand, and appraise health information from electronic sources and apply this knowledge gained to addressing or solving a health problem" [41]. eHealth literacy comprises both general skills and specific skills. General skills include reading, writing, and numeracy, media literacy, and information literacy (ie, information seeking and understanding). Specific skills include computer literacy (information technology skills), health literacy, and science literacy [42,43]. eHealth literacy involves a mix of health, information, scientific, computer, and Internet literacy [44]. In an electronic world where information and communication technology design enables the delivery of health-related information, being health literate requires an expanded set of skills to engage in health promotion and sustain personal health [41,44]. People with higher education are more likely to download health information to a mobile device [45]. Higher educational attainment and younger age are associated with higher eHealth literacy [46]. Rather than being static, both health literacy and eHealth literacy are influenced by an individual's health status, motivation, education, and changes in technology [34]. Among people with lower socioeconomic status, inequalities likely exist with respect to use of digital resources and online skills [46]. The digital divide relates both to Internet access and to the gap between people who can effectively use new information tools and those who cannot [4].

The model of ehealth literacy proposed by Norman and Skinner, eHEALS, defines the concept using 6 sub-literacies (traditional, information, media, health, computer, and scientific literacy). Eight statements are included (eg, I know how to find helpful health resources on the Internet, I know how to use the health information I find on the Internet to help me) about an individual's perception of their eHealth literacy measured on a 5-point Likert scale [41]. The eHealth Literacy Assessment Toolkit (eHLA) developed by Furstrand and Kayser [47] provides tools for assessing a user's familiarity with computers, confidence in using computers, and health literacy. The eHLA toolkit is based upon the work of previous authors [41,48,49]. There has also been interest in developing computer-based health literacy screening instruments suitable for eHealth apps. However, there is currently a lack of information about the psychometric properties of computer-based health literacy instruments [50].

Little information is available about the general cognitive motivators that prompt people's use of health apps [14]. People who are more health conscious are more likely to use health apps, partly because apps are often used to avoid unhealthy situations or to manage one's own health condition (eg, obesity, breast cancer). People with higher levels of health consciousness are more likely to have preventive health behaviors (eg, healthy eating habits, exercise, and avoidance of smoking) and actively seek health information from various sources including the Internet [14,51,52]. The concept of self-efficacy, highlighted in Bandura's social cognitive theory, has been extended to Internet health information use efficacy [53]. Health app use efficacy refers to a person's cognitive ability to use health apps in order to access health information [14]. Scales have been proposed to measure people's health consciousness, health information orientation, and health app use efficacy [14,52].

Regulatory Issues

In some countries, government agencies have begun to regulate or curate medical apps [54-56]. There is concern about both patient safety and the security and confidentiality of patient data transmitted and stored in mobile medical apps [55]. In 2013, the US Food and Drug Administration (FDA) has released guidance for mobile medical apps that draw a distinction between unregulated apps and mobile medical apps that are subject to overt FDA regulation [57]. Apps that convert a mobile platform such as a smartphone or tablet computers into a medical device are regulated by the FDA [55]. The FDA regulates mobile apps that pose a greater risk to patients if they do not function as intended (eg, apps that perform clinical tests such as blood or urine analysis, apps that display diagnostic images from X-rays and magnetic resonance imaging, and those that remotely display data from bedside monitors). Apps for general health education are mostly unregulated [57]. In the United States, Health Insurance Portability and Accountability Act (HIPAA) regulations require covered entities and their business associated (eg, physicians, hospitals, and health plans) to protect health information that identifies an individuals and that relates to an individual's physical or mental health or health care services to the individual [58]. Mobile app developers must consider whether the software will be used by a covered entity and whether it will include any protected health information. For example, an app that assists a health care provider with following up patients would need to be designed to allow the provider to comply with HIPPA [58]. In the United Kingdom, the National Health Service established a Health Apps Library which endorses apps that are considered to be relevant to people in Britain, provide trustworthy information, comply with data

storage regulations, and do not pose potential risks if they are used improperly [59]. A recent assessment of 79 apps certified as clinically safe and trustworthy by the Health Apps Library found systematic gaps in compliance with data protection principles [60]. None of the 79 apps encrypted personal information stored locally, 66% (23 of 35) of apps sending identifying information over the Internet did not use encryption, and 20% (7 of 35) did not have a privacy policy [29]. The authors noted that app users cannot see into the inner workings of apps or the services they connect to; hence, they must trust developers to comply with privacy regulations and security best practices [29]. Medical information stored on apps should be secured using encryption [61]. Systematic reviews of health and wellness apps available from generic app stores have identified deficiencies in the extent to which data users are documented and appropriate security measures are implemented [62,63].

Conclusions

Additional cancer prevention and control research is needed to examine the efficacy of mobile phone apps [64]. Future studies should utilize randomized controlled trial research designs and adequate sample sizes to better explore the cancer prevention capabilities of mobile phones. The efficacy and effectiveness of mobile phone apps that are already in routine use—for example, the National Cancer Institute's QuitPal app [65]—should be examined in well-designed randomized controlled trials. There is a need for culturally tailored health messages to increase awareness of behaviors associated with reduced cancer risk such as smoking cessation and sun safety. Research-tested mobile phone apps are also needed for non-English speakers or for persons with low health literacy.

Conflicts of Interest

None declared.

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Abbreviations

ACT: acceptance and commitment therapy
eHLA: eHealth Literacy Assessment Toolkit
FDA: Food and Drug Administration
HIPAA: Health Insurance Portability and Accountability Act REALM: Rapid Estimate of Adult Literacy in Medicine
REALM–R: the Shortened Rapid Estimate of Adult Literacy in Medicine
S-TOFHLA: Shortened Test of Functional Health Literacy in Adults
TOFHLA: Test of Functional Health Literacy in Adults

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Original Paper

Walking as a Contributor to Physical Activity in Healthy Older Adults: 2 Week Longitudinal Study Using Accelerometry and the Doubly Labeled Water Method

Giulio Valenti[1], MS Eng; Alberto G Bonomi[2], PhD; Klaas R Westerterp[3], PhD

[1]Department of Human Biology, Maastricht University, Maastricht, 6200 MD, Netherlands

[2]Personal Health Solutions, Philips Research Laboratories, Eindhoven, Netherlands

[3]Department of Human Biology, Maastricht University, Maastricht, Netherlands

Corresponding Author:
Giulio Valenti, MS Eng
Department of Human Biology
Maastricht University
Universiteitssingel 50
Maastricht, 6200 MD, PO Box 616
Netherlands
Phone: 31 433882124
Fax: 31 433670976
Email: g.valenti@maastrichtuniversity.nl

Abstract

Background: Physical activity is recommended to promote healthy aging. Defining the importance of activities such as walking in achieving higher levels of physical activity might provide indications for interventions.

Objective: To describe the importance of walking in achieving higher levels of physical activity in older adults.

Methods: The study included 42 healthy subjects aged between 51 and 84 years (mean body mass index 25.6 kg/m^2 [SD 2.6]). Physical activity, walking, and nonwalking activity were monitored with an accelerometer for 2 weeks. Physical activity was quantified by accelerometer-derived activity counts. An algorithm based on template matching and signal power was developed to classify activity counts into nonwalking counts, short walk counts, and long walk counts. Additionally, in a subgroup of 31 subjects energy expenditure was measured using doubly labeled water to derive physical activity level (PAL).

Results: Subjects had a mean PAL of 1.84 (SD 0.19, range 1.43-2.36). About 20% of the activity time (21% [SD 8]) was spent walking, which accounted for about 40% of the total counts (43% [SD 11]). Short bouts composed 83% (SD 9) of walking time, providing 81% (SD 11) of walking counts. A stepwise regression model to predict PAL included nonwalking counts and short walk counts, explaining 58% of the variance of PAL (standard error of the estimate=0.12). Walking activities produced more counts per minute than nonwalking activities (P<.001). Long walks produced more counts per minute than short walks (P=.001). Nonwalking counts were independent of walking counts (r=−.05, P=.38).

Conclusions: Walking activities are a major contributor to physical activity in older adults. Walking activities occur at higher intensities than nonwalking activities, which might prevent individuals from engaging in more walking activity. Finally, subjects who engage in more walking activities do not tend to compensate by limiting nonwalking activities.

Trial Registration: ClinicalTrials.gov NCT01609764; https://clinicaltrials.gov/ct2/show/NCT01609764 (Archived by WebCite at http://www.webcitation.org/6grls0wAp)

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KEYWORDS

aging; walking; physical activity; accelerometry; monitoring, ambulatory/instrumentation

Introduction

Aging is accompanied by reduced physical activity (PA) and increased sedentary behavior [1-3]. The time spent by older adults in moderate to vigorous PA decreases from 30 minutes/day in individuals in their seventh decade to 10 minutes/day in individuals older than 80 years [4]. Reduced PA is associated with reduced mobility [5] and decreased life expectancy [6,7]. To contrast this trend, the World Health Organization guidelines suggest that subjects older than 65 years should be moderately active for at least 150 minutes/week in bouts longer than 10 minutes [8]. Although a variety of activities are carried out during the day, it is unknown which one is more effective in increasing PA.

Among the activities of daily living, walking is of major importance. Walking is an indicator of overall well-being and walking speed is an indicator of life expectancy. Independent living strongly depends on walking, which allows individuals to accomplish many tasks of daily living [9]. Furthermore, walking is a highly prevalent form of PA in healthy older individuals, who reportedly walk as much as when they were younger and more physically active [10]. In spite of its relevance, the role of walking in PA has not yet been described and it is unclear whether active people actually walk more. Individuals who frequently engage in walking activities might compensate by decreasing nonwalking activities, such as biking, practicing sports, housekeeping, or climbing stairs, ultimately resulting in similar levels of PA as individuals less inclined to walk. The definition of the role of walking in PA might provide more activity-specific insights as well as intervention indications.

Quantification of walking activity can be provided by inertial sensors such as pedometers [11,12] or accelerometers [13,14]. Both pedometers and accelerometers offer the possibility to monitor walking activities over time. Pedometers only measure number of steps, whereas more information, including nonwalking activities, might be derived from accelerometers. To date, studies where walking patterns are described by means of an accelerometer have not integrated the results of overall PA, leaving out the effects of nonwalking activities [15,16]. This study aimed at describing the importance of walking in achieving higher levels of PA, as measured using doubly labeled water in older adults.

Methods

Population

The population included 35 subjects from a previous study and 7 subjects with similar characteristics [17]. All 42 healthy subjects (19 males and 23 females) aged between 51 and 84 years (mean body mass index 25.6 kg/m^2 [SD 2.6]) were recruited by advertisements in local newspapers (Table 1). After signing a written informed consent form, respondents completed a questionnaire including information regarding orthopedic conditions, neurological disorders, and cardiovascular problems that could affect the study. The questionnaire was discussed during a medical visit with a doctor. All subjects were in good orthopedic, neurological, and cardiovascular health and were therefore included. The study was conducted according to the Declaration of Helsinki, and the Ethics Committee of the Maastricht University Medical Center approved the study. This trial was registered at ClinicalTrials.gov as NCT01609764.

Table 1. Subject characteristics (N=42, 19 males).

Characteristic	Mean (SD)	Range
Age, years	65 (8)	51-84
Height, m	1.69 (0.10)	1.47-1.89
Body mass, kg	73 (11)	40-95
BMI[a], kg/m^2	25.6 (2.6)	18.6-30.0

[a] BMI: body mass index.

Study Design

Physical activity, walking, and nonwalking activity were monitored with an accelerometer for 2 weeks. Additionally, total energy expenditure (TEE) and basal metabolic rate (BMR) were measured in a representative subgroup of 31 randomly selected subjects. Physical activity level (PAL) was then calculated as the ratio of TEE to BMR [18].

Walking Recognition Algorithm

Subjects wore a triaxial accelerometer (GT3X+, ActiGraph, Pensacola, FL) on the lower back using a belt, as described before [18]. Accelerometry data were collected in the laboratory and in daily life at a sampling rate of 60 Hz. During the laboratory session, subjects performed treadmill walking at 4 different speeds. Such data were used to define parameters of the algorithm used to detect walking activities. A personalized template prototype of the acceleration signal was derived from the treadmill data for each subject, as described before [17]. Accelerometer data were analyzed as vector magnitude and segmented into epochs of 5 seconds. The acceleration signal from each epoch was cross-correlated with the personalized template. The standard deviation of the acceleration signal (SDs) and the standard deviation of the cross-correlation function output (SDcc) were calculated for all epochs. SDs and SDcc from treadmill epochs were used to fit two probability distributions indicating the likelihood of walking. A Naïve Bayes probability distribution for the laboratory walking data was defined as follows:

$$P(walk) = P(walk \mid SD_s \wedge SD_{cc}) \quad (1)$$

$$P(nonWalk) = 1 - P(walk) \quad (2)$$

Assuming naïve conditional independence,

$$P(walk) = k \times P(SD_s \mid walk) \times P(SD_{cc} \mid walk) \quad (3)$$

with

$$k = P(walk)/P(SD_s \wedge SD_{cc}) \quad (4)$$

$P(SD_s \mid walk)$ and $P(SD_{cc} \mid walk)$ were derived from the data and k was empirically estimated as follows:

$$k = 0.5/(0.14 \times \max(P(SD_s \wedge SD_{cc} \mid walk))) \quad (5)$$

The classifier for each epoch in daily life was constructed as follows:

$$Y=\text{argmax}\,(P(walk), P(non\text{-}walk)) \quad (6)$$

Bouts of walking shorter than 1 minute were classified as short walks, whereas bouts lasting at least 1 minute were classified as long walks.

Counts were calculated by integrating body accelerations of each epoch after detrending and rectification of the signal from each axis. Epochs with less than 10^{-3} counts/second were labeled as inactivity and excluded from further analysis.

Nonwalking counts, short walk counts, and long walk counts per day were calculated integrating counts in the respective epochs over each day. Walking counts were the sum of short walk counts and long walk counts. Activity counts were the sum of walking counts and nonwalking counts. Time spent in each category was measured as 5 seconds multiplied by the respective number of epochs. Days during which data were missing or subjects carried the accelerometer for less than 10 hours were excluded and the average was calculated for the remaining data, assuming that daily PA is an ergodic process where the expected mean does not change after removing a randomly taken sample. Average counts per day were calculated over the days of measurement.

Energy Expenditure

Total energy expenditure was measured during the 2 weeks of measurement using doubly labeled water, according to the Maastricht protocol [19]. Briefly, after the collection of a baseline urine sample on the evening of day 0, subjects drank a weighted amount of $^{2}H_{2}{}^{18}O$. The result is an initial increase in the body water enrichment of about 120 ppm for ^{2}H and about 240 ppm for ^{18}O. Urine samples were then collected in the morning (from the second voiding) of days 1, 8, and 15 and in the evening of days 1, 7, and 14. Samples were analyzed by isotope ratio mass spectrometry (Optima; VG Isogas, Middlewich, Cheshire, UK). Carbon dioxide production was calculated from the difference between the elimination rates of ^{2}H and ^{18}O. Total daily energy expenditure was calculated from carbon dioxide production [20], assuming a respiratory quotient of 0.85. Basal metabolic rate was measured during 30 minutes under a ventilated hood (Omnical; Maastricht Instruments, Maastricht, the Netherlands) on the morning of the first day of measurement in the supine position under standard conditions of rest, fasting, immobility, thermoneutrality, and mental relaxation.

Data Analysis

All variables are expressed as mean (SD). The normality of the data was examined with the Shapiro-Wilk test. The Pearson correlation coefficient (r) was used to describe the association between variables. A linear regression was used to model the relation between activity counts and PAL. The residuals of the model were studied to identify confounding factors. The best predictors of PAL among nonwalking counts, short walk counts, and long walk counts were selected using a stepwise multilinear regression. The statistical significance threshold was set at $P<.05$. MATLAB (MathWorks Inc, Natick, MA, USA) was used for the data elaboration and the figures. SPSS (SPSS Inc, Chicago, IL, USA) was used for the statistical analysis.

Results

Physical activity level ranged between 1.43 and 2.36 (1.84 [SD 0.19] on average, N=31). The activity time of the total group (N=42) was on average 10.5 hours/day (SD 1.7). About 20% of the activity time (21% [SD 8]) was spent in walking activities, which accounted for about 40% of the total counts (43% [SD 11]; Figure 2). The average walking time was about 2 hours/day, indicating that PA was not restricted in this population. Subjects walked in short bouts for 83% (SD 9) of their walking time providing 81% (SD 11) of their walking counts (Table 2).

Higher PAL was achieved by subjects with higher activity time (r=.75, $P<.001$) and activity counts (r=.73, $P<.001$). Specifically, subjects with a higher PAL spent more time in nonwalking activities (r=.64, $P<.001$) and produced more nonwalking counts (r=.61, $P<.001$) than subjects with a lower PAL. The correlation coefficient between PAL and walking, particularly during short walks, was positive but did not reach significance (PAL vs walking time: r=.26, P=.08; PAL vs walking counts: r=.33, P=.07; PAL vs short walk counts: r=.35, P=.05).

Two linear models were developed to identify the best predictors of PAL. A simple linear model based on activity counts could explain 52% of the measured PAL (standard error of the estimate [SEE]=0.13). The residuals of this model correlated with the fraction of walking time spent in short walks (r=−.38, P=.02), suggesting that the prevalence of short walks might be a determinant of PAL. Therefore, a stepwise regression model was developed to predict PAL from one or more variables among nonwalking counts, short walk counts, and long walk counts (Table 3). This second model included nonwalking counts and short walk counts, explaining 58% of the variance of PAL (SEE=0.12).

Walking activities were conducted at higher intensities than nonwalking activities (mean 21.5 [SD 3.0] counts/minute vs mean 7.0 [SD 1.2] counts/minute, $P<.001$). Among walking activities, long walks were conducted at higher intensities than short walks (mean 23.3 [SD 3.6] counts/minute vs mean 20.9 [SD 3.1] counts/minute, P=.001). Walking counts were independent of nonwalking counts (r=−0.05, P=.38; Figure 3).

Table 2. Physical activity and walking activity (N=42); mean (SD).

Variable	Time (minutes/day)	Counts (kcounts/day)	Intensity (counts/minute)
Physical activity	630 (101)	6.2 (1.4)	9.8 (1.2)
Nonwalking activity	500 (97)	3.5 (1.1)	7.0 (1.2)
Walking activity	130 (61)	2.7 (0.9)	21.5 (3.0)
Walks <1 minute	106 (49)	2.1 (0.7)	20.9 (3.1)
Walks >1 minute	24 (17)	0.6 (0.4)	23.3 (3.6)

Table 3. Two prediction equations of physical activity level from accelerometer counts.

Model	Variable[a]	Coefficient	*P* [b]	r^2 [c]	SD[d]	Beta[e]
Linear model						
	Intercept	1.24	<.001		0.11	
	Physical activity	9.70×10^{-5}	<.001	0.53	1.71×10^{-5}	0.73
	Model			0.53		
Multiple linear model						
	Intercept	1.17	<.001		0.11	
	Nonwalking activity	10.92×10^{-5}	<.001	0.38	1.99×10^{-5}	0.68
	Walks <1 minute	13.42×10^{-5}	.001	0.20	3.64×10^{-5}	0.46
	Model			0.58		

[a] Variables included in the model.

[b] Significance level.

[c] Coefficient of determination.

[d] Standard deviation of the coefficient.

[e] Standardized coefficient.

Figure 2. Composition of activity time and activity counts in older adults (N=42).

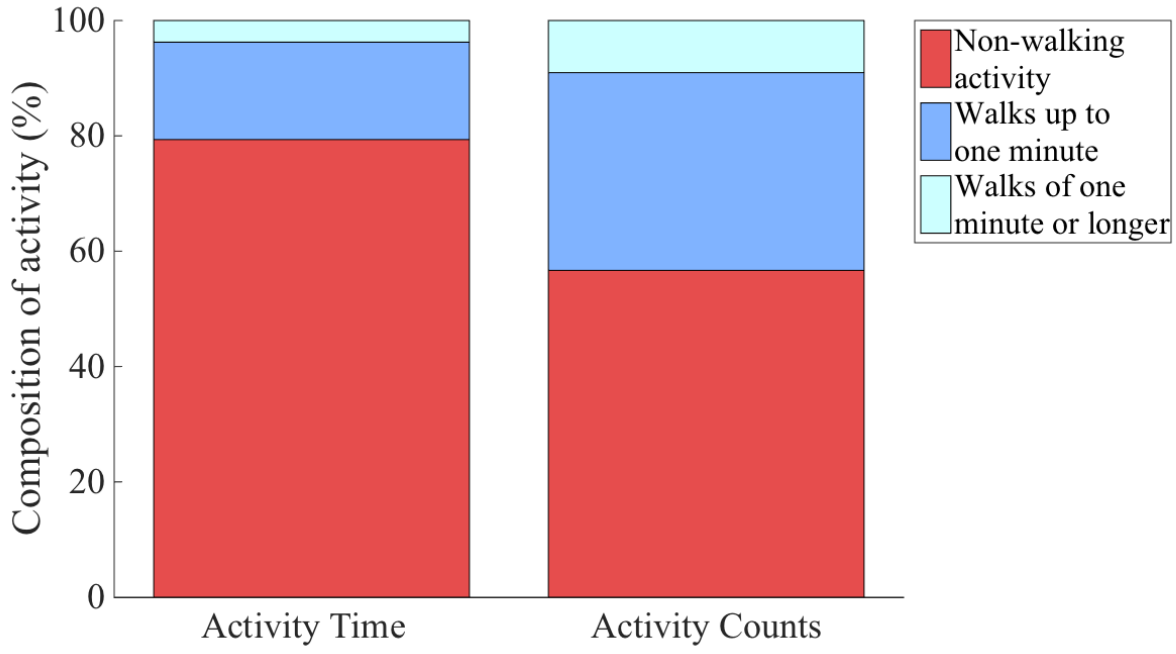
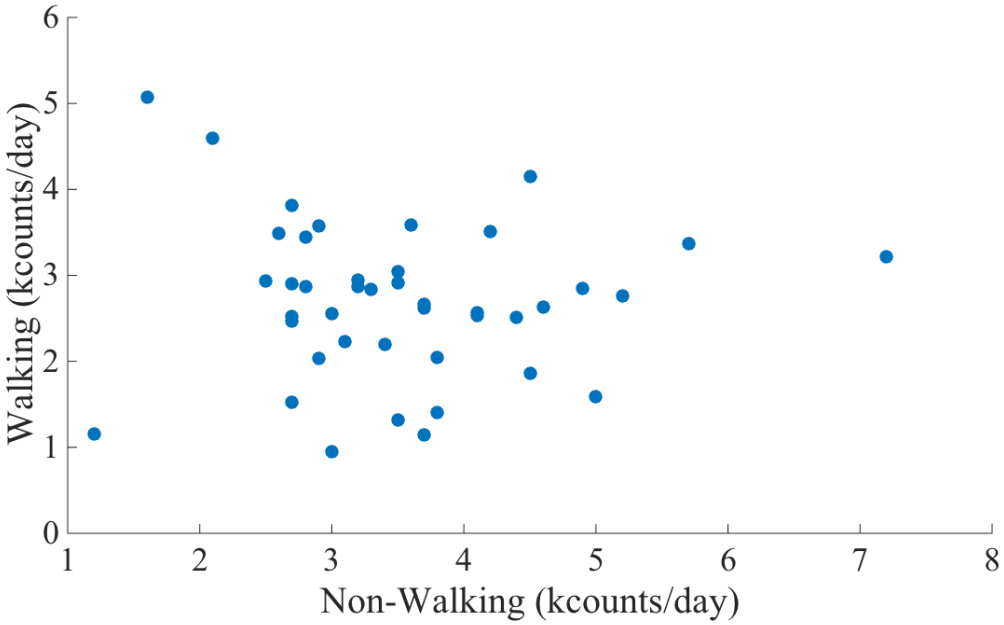


Figure 3. Walking counts versus nonwalking counts in older subjects (N=42).



Discussion

This is the first study that combines accelerometry and the doubly labeled water method to show that walking activities are a major contributor to PA in a population of older adults with a wide range of PAL.

The range of PAL of the subjects in this study is higher than normally reported in healthy older adults [21-23]. The activity time, including all levels of PA, was 10.5 hours/day, which is lower than previous studies where sedentary, moderate, and vigorous activities were reported to add up to 14 hours/day [24], when measured with an accelerometer in older adults. Although different, the results are compatible as in previous studies sedentary time also included periods of inactivity. This study instead excluded inactivity time to focus on PA and in particular on walking.

Walking was a main component of PA providing more than 40% of the activity counts. Despite the relevant proportion of counts, walking time was about 20% of activity time or 2 hours/day. Previous studies reported similar lengths of time spent walking in healthy and independently living older adults [25]. The relevance of walking in daily life is well established [26,27], and walking activity measured with pedometers is often used as a proxy of PA [28,29]. To our knowledge, no study has assessed walking activity as counts so far, preferring number of steps. The number of steps is not comparable to activity counts, whereas the assessment of walking activity as walking counts described in this study allowed to describe the contribution of walking to activity counts. The results showed that walking counts are a relevant proportion of activity counts, although walking time was a relatively small portion of activity time. The short amount of time spent walking is possibly the reason why walking counts only showed a trend with PAL but did not reach significance. Although walking does not seem to explain variations in PAL, its contribution in terms of counts produced remains a major one.

The discrepancy between the proportion of walking counts and the proportion of walking time implies that walking activities occurred at higher intensities and produced more counts per unit of time, compared with nonwalking activities. Walking counts have not been reported before, but previous studies reported that during walking older adults reach 80% of their maximum heart rate and oxygen consumption, concluding that walking intensity in this population is moderate to high [30]. Similarly, it can be observed that long walks were performed at higher intensities than short walks, but over a shorter portion of time. It seems therefore that older adults prefer low-intensity activities and that the high intensity discourages them from engaging in walking and, in particular, long walks. This conclusion is supported by previous studies where walking time in daily life was shown to decrease with increasing intensity [25].

Subjects who engaged in more walking activities did not compensate by reducing nonwalking activities. Although previous studies suggest that PA interventions could suffer from compensatory behaviors outside the exercise time [31-33], these results show that walking is independent of nonwalking. It is therefore reasonable to hypothesize that walking could be less prone to compensatory behaviors and therefore a good candidate for PA interventions.

There is ongoing discussion about whether PA interventions should focus on long walks or short walks [34-36]. The results of this study suggest that subjects tend to prefer shorter walks because of their relatively lower intensity. Short walks also contribute to explaining the variation in free-living PAL and therefore subjects who engaged in more short walks showed higher PAL. These might suggest that short walk interventions could be better tolerated by older individuals and effectively increase their PAL.

The ability of accelerometers to differentiate between activities allowed the detection of walking in this study. Other activities,

such as biking, swimming, rowing, deskwork, housekeeping, or driving, have different acceleration patterns and were classified as nonwalking activities. Algorithms to detect these activities have been described before [37-40] and they could be used to divide the nonwalking category into more specific categories. Given that nonwalking counts partly explained the inter-individual variance in PAL, the detection of different nonwalking activities can provide a more elaborate insight into the composition and determinants of PA.

The population in this study was representative of an active and healthy older population. The findings cannot be generalized to populations with different characteristics without specific studies. Similar protocols could be used in populations that might benefit from increased PA such as obese individuals, diabetic patients, or white-collar workers. Interventions focused on walking in these populations might be effective, but more research is needed to quantify possible compensatory behaviors and to investigate other factors that can contribute to PAL, such as environmental factors, socioeconomic status, and health status.

This study provides reference values for the contribution of walking to PA in healthy older adults, as measured with wearable devices. One possible application of eHealth is in the promotion of PA. A wearable device can reveal subjects' proportion of walking in daily life and provide them with motivational feedbacks.

The results of a previous study suggested that subjects with different walking economy produce different acceleration outputs [17]. This might have implications on the relationship between PAL and activity counts. Future studies might reveal whether walking economy can improve the prediction of PAL with an accelerometer.

In conclusion, walking activities are a major contributor to PA in older subjects with a wide range of PAL, but the relatively high intensity of walking might prevent individuals from engaging in more walking activity. It is also shown that subjects who engage in more walking activities do not tend to compensate by limiting nonwalking activities.

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Authors' Contributions

KRW and GV designed the study. GV collected the data, analyzed the data, and wrote the manuscript. KRW and AGB contributed to the interpretation of the data and reviewed the manuscript. The study was executed under the supervision of KRW. Everyone who contributed significantly to the work has been listed; all authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BMR: basal metabolic rate
PA: physical activity
PAL: physical activity level
SEE: standard error of the estimate
TEE: total energy expenditure

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Original Paper

A Theory-Based Exercise App to Enhance Exercise Adherence: A Pilot Study

Elizabeth C Voth[1], BPhys Ed (Hons), MSc; Nelly D Oelke[2], PhD; Mary E Jung[1], PhD

[1]School of Health and Exercise Sciences, Faculty of Health and Social Development, University of British Columbia: Okanagan, Kelowna, BC, Canada
[2]School of Nursing, Faculty of Health and Social Development, University of British Columbia: Okanagan, Kelowna, BC, Canada

Corresponding Author:
Mary E Jung, PhD
School of Health and Exercise Sciences
Faculty of Health and Social Development
University of British Columbia: Okanagan
3333 University Way
ART 360
Kelowna, BC, V1V1V7
Canada
Phone: 1 250 807 9670
Fax: 1 250 807 8085
Email: mary.jung@ubc.ca

Abstract

Background: Use of mobile health (mHealth) technology is on an exponential rise. mHealth apps have the capability to reach a large number of individuals, but until now have lacked the integration of evidence-based theoretical constructs to increase exercise behavior in users.

Objective: The purpose of this study was to assess the effectiveness of a theory-based, self-monitoring app on exercise and self-monitoring behavior over 8 weeks.

Methods: A total of 56 adults (mean age 40 years, SD 13) were randomly assigned to either receive the mHealth app (experimental; n=28) or not to receive the app (control; n=28). All participants engaged in an exercise goal-setting session at baseline. Experimental condition participants received weekly short message service (SMS) text messages grounded in social cognitive theory and were encouraged to self-monitor exercise bouts on the app on a daily basis. Exercise behavior, frequency of self-monitoring exercise behavior, self-efficacy to self-monitor, and self-management of exercise behavior were collected at baseline and at postintervention.

Results: Engagement in exercise bouts was greater in the experimental condition (mean 7.24, SD 3.40) as compared to the control condition (mean 4.74, SD 3.70, P=.03, d=0.70) at week 8 postintervention. Frequency of self-monitoring increased significantly over the 8-week investigation between the experimental and control conditions (P<.001, partial η^2=.599), with participants in the experimental condition self-monitoring significantly more at postintervention (mean 6.00, SD 0.93) in comparison to those in the control condition (mean 1.95, SD 2.58, P<.001, d=2.10). Self-efficacy to self-monitor and perceived self-management of exercise behavior were unaffected by this intervention.

Conclusions: The successful integration of social cognitive theory into an mHealth exercise self-monitoring app provides support for future research to feasibly integrate theoretical constructs into existing exercise apps. In addition, findings provide preliminary support for theory-based apps to increase self-monitoring and exercise behavior in comparison to a control, no-app condition.

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KEYWORDS

exercise; mHealth; app; self-monitoring; behavior change; social cognitive theory

Introduction

Benefits of Exercise

The benefits of exercise are irrefutable [1] and have been demonstrated for individuals of all ages [2]. In Canada, the government encourages engagement in exercise through the publication of the Canadian Physical Activity and Sedentary Behaviour Guidelines Handbook [3]. While it is often assumed that knowledge of the benefits of exercise will increase exercise levels, informational campaigns have been rendered as ineffective for sustaining behavior change [4,5]. This is exemplified by the steady decline in physical activity and fitness levels among Canadians [2] despite the promotion of these physical activity guidelines, with only 15% of Canadian adults currently meeting daily physical activity recommendations [6]. Similar levels of engagement are seen within the United States [7] and Australia [8], with less than 50% of the respective populations engaging in adequate levels of physical activity.

Mobile Health (mHealth) Technology

One strategy that may provide an effective medium to target physical inactivity at the population level is mobile health technology. To date, there are nearly 7 billion mobile phone subscriptions worldwide, with the use of mobile devices reaching 90% in developing countries and 96% globally [9]. This widespread use of mobile devices has led to the creation of mobile health-based (mHealth) products. Simultaneously, advances in technology have shifted traditional means of health promotion materials from read-only (eg, pamphlets and websites with read-only content) to interactive and responsive means (eg, mobile apps). mHealth apps offer many advantages over traditional informational materials. Data from users can now be analyzed in a context-appropriate, timely, and sophisticated manner [7]. More than ever before, there is opportunity to provide real-time support to the masses, outside of costly traditional personal training or counseling appointment times.

As of 2012, 84% of mobile phone owners had downloaded at least one app to their phone; 19% of those individuals had downloaded an app specifically related to tracking or managing a health-related behavior[10]. The continually increasing prevalence of app use further demonstrates the potential reach for mHealth exercise interventions. While app use is increasing in popularity, existing apps are not without limitations.

Use of Evidence-Based Strategies

The majority of health-related apps currently available are developed on the traditional dissemination model. Generic, automated text messages are typically sent to individual users on a standardized time of day or week, or access to content is on a dedicated website in which users are referred to go read. While these apps provide valuable information to the user, such apps have neglected to integrate evidence-based strategies from established health behavior change theories [7,11-13]. In a 2012 review of the *Health and Fitness* category in the Apple App Store, Cowan and colleagues [11] concluded that there was an overarching lack of theoretical constructs used within 127 surveyed apps. Similar findings were reported in Direito and colleagues' 2014 study evaluating the presence of 26 behavior change techniques in the 40 most popular physical activity and dietary apps from the Apple App Store [14]. While some incorporation of behavior change techniques is evident, Direito and colleagues' conclusions remained consistent with Cowan's review, in that an absence of behavior change strategies exists in physical activity and dietary apps [14]. Cowan, Direito, and colleagues are not alone. Several other reports have also strongly recommended that future apps in the health domain be improved by incorporating evidence-based practices that are known to enhance health behavior change [11,15-17]. These findings highlight the need for collaboration between health behavior change experts and app developers.

Although rare to find, research-derived programs such as the Heart Exercise And Remote Technologies (HEART) mobile phone trial [18] demonstrate the benefits of integrating evidence-based behavior change strategies. Having established utilizing principles of behavior change from social cognitive theory [19], HEART uses a personalized, automated package of text messages aimed at increasing levels of exercise behavior in individuals with ischemic heart disease. HEART short message service(SMS) texts were developed to assist users with goal setting, exercise scheduling, and self-efficacy to overcome exercise barriers and engage in regular exercise in a positive and cost-effective manner.

As demonstrated in the HEART trial, social cognitive theory is particularly well suited for mHealth interventions, as the tenets of the theory are grounded in (1) self-monitoring, (2) self-evaluation, and (3) modification of current behavior based on this self-reflection [20,21]—tasks that mHealth apps have the capacity to assist the user with. The majority of apps allow the user to record their exercise sessions as a form of self-monitoring. Relatedly, many apps allow the user to look back at past exercise sessions in a summative format (eg, number of sessions completed last week)—an opportunity for self-evaluation and reflection. A main tenet within social cognitive theory is self-efficacy. Self-efficacy is a set of beliefs one has about his/her ability to organize and complete a task in order to accomplish a certain task that is crucial for eliciting health behavior change [22]. Self-efficacy is an important predictor to exercise adherence, with numerous trials demonstrating the significant association between improvements in self-efficacy and exercise adherence [23]. Together, these tasks provide the opportunity for the user to modify current behavior in order to meet one's goals. As such, most mHealth apps have the capacity to allow the user to self-regulate behavior based on past experience and future goals, if guided appropriately. Results of the HEART trial support the continued use of SMS texts to increase exercise engagement through a significant main effect for leisure time physical activity in those receiving the SMS theory-based texts, which was mediated by task self-efficacy.

Importance of Self-Monitoring

The success of self-regulation is partly dependent on the fidelity, consistency, and timeliness of self-monitoring [24]. Given the instantaneous nature of real-time feedback that mHealth apps can provide, self-monitoring may be carried out promptly and accurately with minimal inconvenience for the individual.

However, the process of self-monitoring is not simply an audit of one's performance [20], and the act of self-monitoring alone is not likely to help an individual self-regulate. Further investment must be taken by looking at past exercise patterns and recognizing barriers. This provision of feedback can provide the individual with an opportunity to evaluate behavior when necessary to remain in line with one's goal.

Tailored Feedback

While active engagement in self-monitoring and self-regulation are essential for the maintenance of health-related behavior, it is also imperative to provide individuals with personalized feedback on their behavior [25]. Personalized interventions have been demonstrated to be more effective than nonpersonalized interventions at changing health behavior [25]; however, few interventions utilize this technique. Likewise, a systematic review of SMS-based behavior change interventions confirmed the effectiveness of tailored SMS messages for promoting health behavior change (see literature review by Fjeldsoe et al [25]). In the context of mHealth apps, a personalized intervention would allow a health professional to provide tailored feedback to an individual user in a time-efficient manner.

This Study

This pilot study sought to examine the utility of a theory-based exercise self-monitoring app for increasing independent exercise adherence over 8 weeks. It was hypothesized that the use of this app would result in (1) more frequent exercise bouts, (2) more frequent self-monitoring, (3) higher perceived self-management of exercise behavior, and (4) higher self-efficacy to self-monitor exercise behavior in comparison to individuals not using the app.

Methods

Overview

The study was approved by the University of British Columbia: Okanagan Research Ethics Board. A randomized experimental pilot study design was utilized with participants being randomly selected to one of two conditions—the experimental, app-use condition, or the control, no-app condition. Those randomized to the experimental condition used the app for the 8-week investigation, whereas during the same time period, those randomized to the control condition did not have access to the app. The research assistant met with all participants at both baseline and post-testing time points.

Participants

Participants were recruited from a local YMCA fitness facility by means of announcements in fitness classes, posters located throughout the facility, and an information booth in the lobby. In addition, front desk YMCA staff members were instructed to inform individuals about the study opportunity. Eligible participants were current facility members aged 19-70 years, with access to a mobile device. A total of 94 individuals expressed interest in participating. Following initial screening via email, 56 members were deemed eligible (see Figure 1 for detailed information regarding eligibility); they were then randomized through a computer random numbers-generated table to either the experimental condition, which received the app for 8 weeks (18/28, 64% female), or to the control condition, which did not receive the app (20/28, 71% female). While no specific exercise criteria was set, in meeting with the individual participants it became clear that 2 individuals out of 56 (4%) were excessively active and were engaging in competitive athletic events. These 2 individuals were designated not eligible for participation.

Procedures

Overview

Eligible participants provided written consent and subsequently completed baseline questionnaires. All participants then engaged in a goal-setting discussion using the *specific*, *measureable*, *attainable*, *relevant*, and *time-bound* (SMART) goal-setting framework to self-set a weekly exercise frequency goal (eg, I will visit the gym 3 days this week) for the 8-week study duration.

Experimental Condition Protocol

Each participant's profile was created on the app within 24 hours, at which time he/she was prompted by a text message to sign in and begin monitoring exercise behavior. Participants were encouraged to monitor exercise behavior on a daily basis (ie, record exercise into the app), regardless of whether purposeful exercise was planned or completed that day—from here on referred to as *check-in*. Planned nonexercise days were personalized within the app based on planned bouts of exercise for each week (ie, if an individual's goal was to exercise three times per week, that participant's program included 4 *rest*). Participants in the experimental condition were reminded via text message to check in to the app if they had not checked in by 9:00 p.m., regardless of whether they exercised or not that day.

At the beginning of each week, participants were sent a message based on social cognitive theory. Messages ranged from 65 to 135 words in length, and were delivered via the app messaging system, to which users were alerted via a text message. These theory-based messages targeted the components of self-monitoring, verbal persuasion, performance accomplishment, and vicarious experience (see Table 1).

In the event of three consecutive missed check-ins, app users were contacted by the research assistant via SMS text message. If this progressed to four consecutive missed check-ins, the research assistant phoned the participant to discuss any difficulties encountered.

Control Condition Protocol

Following goal development, participants in the control condition were encouraged to implement their newly developed goals over the following 8 weeks. Control condition participants did not receive any support from the research assistant throughout the 8-week duration of the study.

Follow-Up Protocol for All Participants

At the beginning of week 8, participants in both conditions were contacted via email to schedule a 30-minute follow-up interview

for the following week. During this interview, participants completed the poststudy questionnaire.

Measures

Demographics

Participants were asked to provide basic demographic information, including year of birth (see Table 3), height, weight—presented as mean body mass index (BMI) in Table 3—sex, highest level of education completed, and current occupational status (see Table 4 in Results).

On the fourth day of each week, a second message was sent through the app, delivering tailored feedback and support based on the participant's personal performance that week. Daily performance was measured on a 5-star rating system (ie, 5 stars represented complete goal achievement for that day and 3 stars represented partial goal achievement for that day). An additional message was sent through the app if a participant failed to check in to the app on 2 consecutive days (see Table 2).

Figure 1. Participant flow.

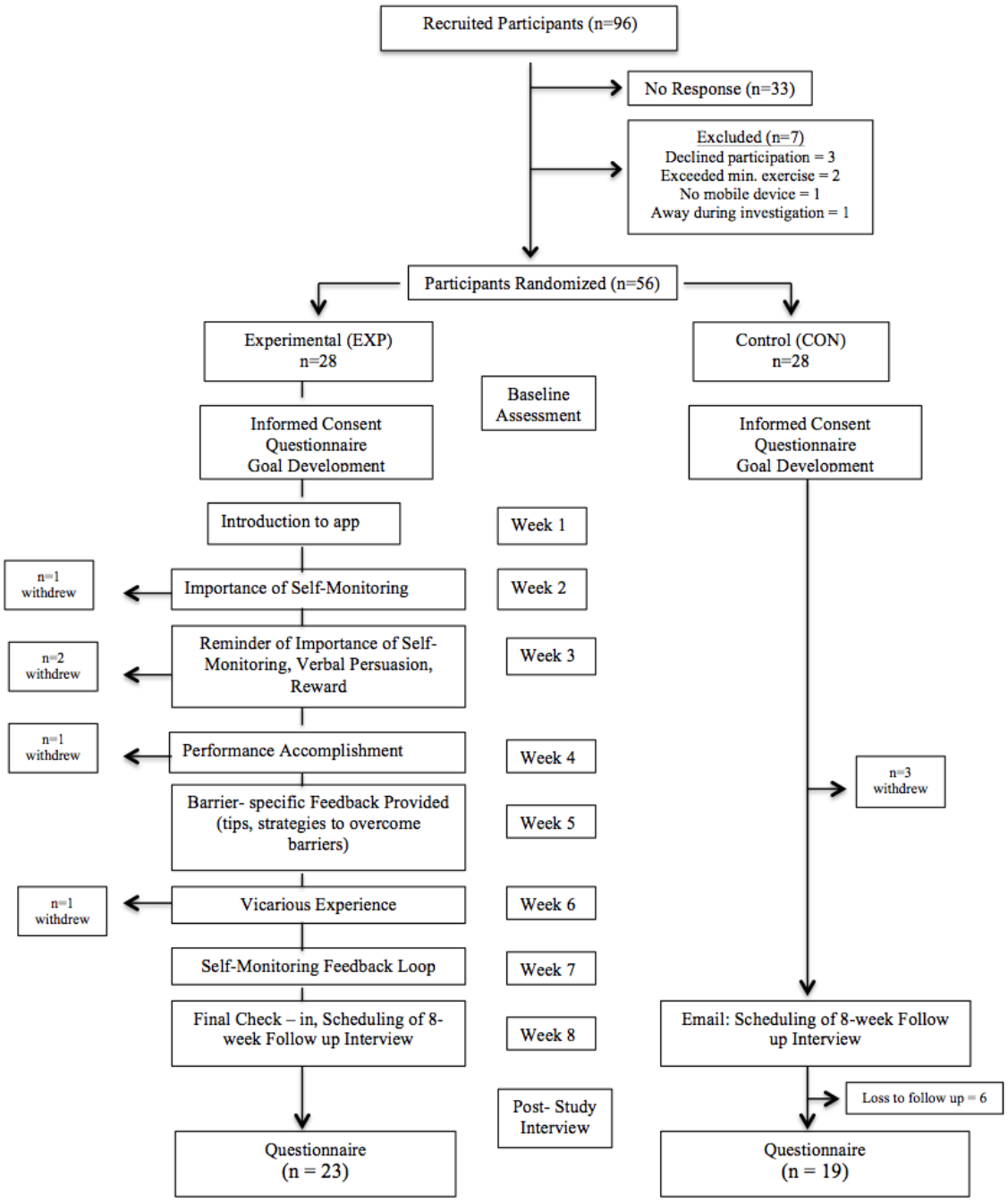

Table 1. Overview of weekly theory-based messages to participants.

Week	Message type	Theoretical content
1	Introduction (establishing rapport)	Hi (insert name)! My name is (insert counselor's name) and I am your virtual exercise counselor. I can't wait to see the progress you make as you monitor and modify your behavior. I know you are super motivated and ready to kick start your exercise so let's get you moving! Check in each day to report your activity and keep an eye on your message center. I'll be checking in frequently to see how you're doing. Feel free to contact me if you have any questions or concerns.☺
2	Importance of self-monitoring	Hey (insert name)! Just wanted to say you're doing a great job! You're already 1 week into using this app and you have tracked your behavior each day! Keeping track of your behavior allows you, and me, to see what a great job you are doing, and helps remind you of your goals. It can also show us where improvements are needed or whether there are any patterns that are problematic. Some people say that keeping track of what exercise they have done is the hardest part—you are excelling in this and this is what will keep you accountable to your personal goals! Keep checking in everyday and let's rock this!
3	Reminder of importance of self-monitoring, use of verbal persuasion, and self-set rewards	Week 2 down and look at how far you have come! You have now been tracking your exercise behavior for 2 weeks. Keep in mind that self-monitoring is the key to making lasting behavior changes. With this app, tracking your behavior is easy and you are showing yourself that you can do it. You are holding yourself to those goals that you care about so much—doesn't it feel great? Now is a great time to plan a reward for yourself. Keep up the great work performing and monitoring your exercise—you can do it!
4	Performance accomplishment	(insert name)—Wow look at all you've done so far! Take a look at your progress graph—all of those green bars you've accumulated are proof that you are well on your way to achieving your goals! You really are using this app to its full potential and you are in control of your exercise. You are doing fantastically—keep up this great momentum.
5	Feedback tailored to participant's goals/overcoming perceived barriers	Example: Barrier = family time As the weather gets warmer, take the family out on the weekend to kick around a soccer ball, ride bikes, or walk to the park and toss a Frisbee.
6	Establishing vicarious experience	Did you know that you are not the only one going through this program right now? There are 40 other facility members just like you that are monitoring their exercise, trying to achieve their personal exercise goals, and using this app to help them reach those goals. These individuals have been recording their bouts of exercise on the app, and have been overcoming their exercise barriers. So far, the app has been keeping people honest and committed to their exercise goals.
7	Self-monitoring feedback loop	It's week 7! You're doing such a fantastic job taking charge of your own exercise regime by consistently monitoring your behavior and achieving positive scores each day. Now is a good time to look back and search for patterns of when you typically find it most difficult to stick with your exercise regimen. This can give you clues on how to circumvent those less-than-optimal motivational days. Notice weekends are your weak point? Be sure to get all your exercise in during the week and take the weekends off on purpose! Finding AM workouts unbearable? Modify your nighttime routine so that getting up and out the door isn't so hard. By seeking out problematic trends, you can revise your plans and will be more likely to succeed.
8	Final check-in	Today marks the final week of goal tracking for the study. Think about where you started and look at where you are now, the physical and mental barriers that you have been able to break down, and all about what you have learned about yourself. You are in control of your behavior and you are in the habit of self-monitoring. You should feel proud of the progress you've made. Now use this feeling to rock your last week of workouts and use this as you move forward. Great job!

Table 2. Exercise counselor intervention timeline.

Achievement	Intervention message
Complete daily goal achievement	*First occurrence* Great job yesterday! You successfully completed all your set goals and rocked it! Keep up the great work. *Continuous achievement* (Do not repeat until 1 week after first congratulatory message) Wow! You continually rock it! You're a rock star! Keep up the good work! You deserve a gold star. Keep rocking it!
Partial daily goal achievement	You've had some challenges but you did it! Good job for facing your barriers and getting out there. Keep up the good work.
Partial goal achievement on multiple days	Good job for checking into the app. I know that can be hard when barriers present themselves but you are aware of what is not working. I know you are able to reach those goals you set out to achieve. You can do this!
Missed check-in for 2+ days	Hey (insert name)! Just checking in to see how it's going! 2 days have gone by since you last checked in to the system. Every day is a new one so let's get you back on track and start monitoring that exercise! The hardest part is checking in and keeping track of what you are doing. If you have any questions or concerns please do not hesitate to contact me.

Table 3. Mean age and body mass index of participants.

Participant characteristics	Control group	Experimental group
Age (years), mean (SD)	41.53 (10.90)	37.45 (14.13)
BMI[a] (kg/m^2), mean (SD)	25.87 (3.60)	28.24 (6.50)

[a]BMI: body mass index.

Self-Reported Exercise

Purposeful exercise behavior was measured using the Godin Leisure Time Exercise Questionnaire (GLTEQ) [26] at baseline and postintervention (ie, 8 weeks). Participants were asked to report the frequency in which they engaged in moderate (eg, fast walking) and strenuous (eg, jogging) activity during their free time over the past 7 days. The GLTEQ asks participants to report exercise bouts of 30 minutes or more, as recommended by Amireault and Godin [27]. Consistent with past literature [27,28], moderate and strenuous bouts of exercise were summed together for analyses.

Self-Monitoring of Exercise Behavior

Assessing the frequency of self-monitoring throughout the 8-week study duration required condition-specific measures. At baseline, all participants' self-reported the frequency of their self-monitoring exercise behavior over the past 7 days. Postintervention, frequency of self-monitoring exercise behavior among the app users (ie, experimental condition) was assessed using the total number of completed app check-ins, averaged over the 8-week duration of the study. Participants in the control condition were asked to provide an average weekly self-monitoring frequency over the previous 8 weeks.

Self-Management of Exercise Behavior

Self-management of exercise was measured using six items from Hallam and Petosa's [29] measure of self-regulation. Responses were rated on a 5-point Likert scale ranging from 1 (*strongly disagree*) to 5 (*strongly agree*). Relevant items selected assessed plans to participate in exercise (ie, It is difficult for me to find opportunities to participate in exercise) and confidence to self-manage time (ie, I am able to find or make time to participate in exercise). These items were modified from the original measure by replacing the reference from "my condition" to "exercise." Cronbach alpha values at pre- and postintervention (alpha>.8) suggest a reliable relationship for analysis [30,31].

Self-Efficacy to Self-Monitor Exercise

Self-efficacy to self-monitor (SESM) exercise was assessed using three items. Participants rated their confidence to self-monitor exercise bouts on an 11-point Likert scale ranging from 0% (*not at all confident*) to 100% (*extremely confident*). The items assessed participants' confidence to record exercise (ie, record your exercise bouts), track and adjust behavior (ie, keep track of how many times you exercise and adjust your behavior accordingly), and manage their daily schedule to allow for exercise (ie, manage your daily schedule to allow time for participation in exercise) over the next 7 days. The three items were averaged to reflect an overall SESM score. In this study, scores derived from this instrument demonstrated acceptable levels of reliability (Cronbach alpha>.7) at both pre- and postintervention [30,31].

Analytic Plan

Data were analyzed using SPSS Statistics version 21 (IBM Corp). A series of independent *t* chi-square tests were conducted to examine equivalency between conditions on all demographic, dependent, and independent variables at baseline. Repeated-measures analyses of variance (ANOVA) were used to test the hypotheses that exercise bouts, self-monitoring exercise, self-efficacy to self-monitor, and self-management of exercise will be greater in the experimental condition as compared to the control condition following the 8-week study period. All effects are reported as significant at $P<.05$. Effect size estimates were calculated using partial eta squared (partial

η^2) for ANOVA and Cohen's d for *t*. Effect size derived from partial $\eta^2$was interpreted as small (0.01), medium (0.06), and large (0.14) in accordance with conventional practices within the social sciences [32,33]. Likewise, effect sizes derived from Cohen's d were interpreted as small (0.20), medium (0.50), and large (0.80) [33,34]. Differences between conditions and time × condition interactions yielding medium-to-large effect sizes were further explored with *t*.

Results

Demographics

A total of 56 adults—mean age 40 years (SD 13); mean BMI 26.8 kg/m^2 (SD 5.3)—participated in this study, with 36% of participants having achieved a university level degree or higher, and 50% working either part time or full time. A total of 28 individuals out of 56 (50%) were randomized to the experimental condition—mean age 38 years (SD 14); mean BMI 28.2 kg/m^2 (SD 6.5)—and 28 out of 56 (50%) were randomized to the control condition—mean age 42 years (SD 11); mean BMI 25.9 kg/m^2 (SD 3.6). In total, 41 out of 56 participants (73%) provided follow-up data 8-weeks postintervention (see Table 4 for demographic information and Figure 1 for participant flowchart).

There were no statistical differences in demographic, dependent, or independent variables between conditions at baseline with the exception of current exercise self-monitoring behavior. At baseline, participants in the control condition (mean 1.89, SD 2.28) reported a higher frequency of self-monitoring in the past 7 days than participants in the experimental condition (mean 0.52, SD 1.61; t_{37}=-2.34, *P*=.02, d=0.69). There was no statistical difference in dropout rate between conditions (χ^2_1= 1.2, *P*=.28).

Self-Reported Exercise

A repeated-measures ANOVA examining self-reported exercise frequency revealed no main effect for time ($F_{1,38}$=2721, *P*=.11, partial η^2=.067) or condition ($F_{1,38}$= 2.45, *P*=.13, partial η^2=.061). The time (pre, post) × condition (experimental, control) interaction, although not meeting statistical significance, yielded a medium-to-large effect size ($F_{1,38}$= 3.87, *P*=.06, partial η^2=.092). Exploratory post hoc analysis revealed a significant difference between conditions, such that those in the experimental condition (mean 7.24, SD 3.40) were engaging in significantly more bouts of exercise per week than those in the control condition (mean 4.74, SD 3.70; t_{38}= 2.23, *P*=.03, d=0.70) (see Table 5).

Self-Monitoring of Exercise Behavior

A repeated-measures ANOVA examining self-monitoring frequency showed a main effect for time ($F_{1,33}$= 59.55, *P*<.001, partial η^2=.643) and condition ($F_{1,33}$= 15.38, *P*<.001, partial η^2=.318). These main effects were superseded with a significant time (pre, post) × condition (experimental, control) interaction ($F_{1,33}$= 49.39, *P*<.001, partial η^2=.599). Post hoc analysis revealed a significant difference between conditions at postintervention, such that those in the experimental condition (mean 6.00, SD 0.93) were engaging in a significantly higher frequency of self-monitoring compared to the control condition (mean 1.95, SD 2.58; t_{40}= 6.88, *P*<.001, d=2.10) (see Table 5).

Self-Management of Exercise Behavior

A repeated-measures ANOVA examining self-management of exercise behavior revealed no main effect for time ($F_{1,38}$= 1.91, *P*=.18, partial η^2=.048) or condition ($F_{1,38}$=.408, *P*=.53, partial η^2=.011). The time (pre, post) × condition (experimental, control) interaction was not significant ($F_{1,38}$=.039, *P*=.85, partial η^2=.001) (see Table 6).

Table 4. Participant demographic characteristics.

Participant characteristics	Control group (n=28)[a], n (%)	Experimental group (n=28)[b], n (%)
Sex (female)	16 (57)	16 (57)
Education		
Less than high school	0 (0)	0 (0)
High school	5 (18)	5 (18)
Apprenticeship, trades, or diploma	2 (7)	3 (11)
College	4 (14)	4 (14)
University diploma or degree	7(25)	7 (25)
Postgraduate degree	0 (0)	2 (7)
Occupation		
Working full time	8 (29)	9 (32)
Working part time	4 (14)	3 (11)
Working occasionally/contract work	1 (4)	1 (4)
Student	0 (0)	4 (14)
Retired	1 (4)	2 (7)
Other	4 (14)	2 (7)

[a]Only 18 out of 28 control group participants completed these measures.

[b]Only 21 out of 28 experimental group participants completed these measures.

Table 5. Self-reported exercise and self-monitoring frequency.

Category	Control group, average frequency/7 days (SD)		Experimental group, average frequency/7 days (SD)	
	Preintervention	Postintervention	Preintervention	Postintervention
Exercise engagement	4.92 (2.91)	4.74 (3.70)	5.14 (3.14)	7.24 (3.40)
Self-monitoring frequency	1.89 (2.28)	1.95 (2.58)	0.52 (1.61)	6.00 (0.93)

Table 6. Self-management of exercise behavior.

Category	Control group, average frequency/7 days (SD)		Experimental group, average frequency/7 days (SD)	
	Preintervention	Postintervention	Preintervention	Postintervention
Self-management	3.34 (0.82)	3.16 (0.32)	3.42 (0.86)	3.29 (0.29)

Table 7. Self-efficacy to self-monitor exercise.

Category	Control group, average perceived % self-efficacy to self-monitor		Experimental group, average perceived % self-efficacy to self-monitor	
	Preintervention	Postintervention	Preintervention	Postintervention
Self-efficacy to self-monitor	80.70	81.05	83.71	84.70

Self-Efficacy to Self-Monitor Exercise

A repeated-measures ANOVA examining SESM was conducted, revealing no main effect for time ($F_{1,39}$=.092, P=.76, partial η^2=.002) or condition ($F_{1,39}$=.665, P=.42, partial η^2=.017). Further, the time (pre, post) × condition (experimental, control) interaction was not significant ($F_{1,39}$=.021, P=.89, partial η^2=.001) (see Table 7).

Discussion

Principal Findings

This preliminary pilot study investigated the utility of a theory-based self-monitoring app for improving exercise adherence. To our knowledge, this study is the first to integrate behavior change theory in an app, using personalized goals and interaction with a virtual exercise counselor for the promotion

of exercise behavior. Findings provide preliminary evidence that, after 8 weeks, individuals with access to such an app engage in a higher frequency of exercise behavior in comparison to individuals who did not have the app. Specifically, app users reported engaging in 7.2 bouts of exercise per week after 2 months, whereas individuals without use of the app reported engaging in 4.7 bouts of exercise per week at this time period. Although this did not reach statistical significance (P=.06), this difference between conditions on exercise behavior represents a medium-to-large effect size (partial η^2=.092), findings that are similar to those reported in other mHealth trials [35,36]. Possible reasons for these positive findings is that mHealth apps allow feedback messages to be sent in a time-sensitive manner, designed around the individual user to further facilitate communication [36]. Use of an app is found to be a simple self-monitoring tool, serving as a means of encouragement and motivation. When combined with feedback, both visual and verbal, the use of an app encourages users to work toward their activity goals [35].

Findings from this pilot study also provide partial support for our secondary hypothesis that use of a theory-based self-monitoring app will result in a higher frequency of self-monitoring in comparison to individuals without access to an app. From baseline to 8 weeks later, app users' self-monitoring frequency increased from less than one event per week, to an average of six self-monitoring events per week. Self-reported self-monitoring of exercise behavior was unchanged from baseline to post-testing in the control condition (see Table 5). Such an increase in self-monitoring can be partially accredited to the electronic nature of our mHealth app. Electronic diaries facilitate (1) the instantaneous transfer of data between user and counselor or health care provider [37] and (2) have been shown to be associated with higher rates of adherence when compared to traditional self-monitoring via paper and pen diaries [38].

Despite increases in both exercise and self-monitoring behavior, our hypotheses that use of the app would result in an improved self-management of exercise behavior, or self-efficacy to self-monitor exercise behavior was not supported. Use of the app did not result in a significant effect on self-management of exercise from pre- to post-testing time points (see Table 6) or self-efficacy to self-monitor exercise behavior (see Table 7). In regard to the control condition, participants showed no significant change in self-management of exercise or self-efficacy to self-monitor across time points. In light of our nonsignificant findings for self-management of exercise behavior, further evaluation is warranted to understand the manner in which our intervention targeted self-regulatory principles. The purpose of this intervention was to increase the practice of self-monitoring as a key component of self-regulation, and not overcoming exercise barriers. As such, one plausible explanation for the failure to change perceived self-management of exercise behavior in the experimental condition is that this construct was not adequately addressed in the intervention content.

It is also possible the items used to measure self-regulation did not adequately measure the construct within the context of exercise. Although Hallam and Petosa's [29] measure is highly regarded with respect to self-management of a general health condition, it is plausible that the measure was not context appropriate to measure change in exercise behavior. Further, as can be seen by examination of the means for self-efficacy to self-monitor, a possible ceiling effect may have occurred during this intervention, with baseline self-efficacy scores of over 80% being reported by both conditions. Interestingly, Hallam and Petosa [29] also suggested a problematic ceiling effect in their 2004 study integrating social cognitive theory in a work-site intervention. The purpose of this study was to directly impact self-monitoring through tangible use of an app. However, given the widespread use of apps, one possible explanation for the observed ceiling effect is that all participants were familiar with the act of self-monitoring through other generic apps (eg, tracking work or time spent on social media) prior to the investigation, and therefore their belief (ie, self-efficacy) to self-monitor was not significantly impacted through the intervention material.

Strengths and Limitations

The integration of theory into the development of a self-monitoring app was the primary strength of this pilot study. To date, principles from theories of health behavior have been used sparingly within mHealth apps [12], despite evidence to suggest the integration of theory (eg, social cognitive theory) lends support to behavior change [18]. In this study, app users received a social cognitive theory-grounded message once per week over 8 weeks. Such an automated strategy could feasibly be incorporated into many existing mHealth apps. Further, each app user set a personalized 8-week goal, allowing for tailored feedback from a virtual exercise counselor. Lack of tailored feedback has been a limitation in previous trials [35]. The current trial was able to integrate the use of tailored, real-time feedback in a nonburdensome manner, facilitated by one exercise counselor. Daily review of users' self-monitoring was made manageable due to the electronic nature of the app, taking approximately one minute per day per participant to review and respond to users' questions and comments. As the system is developed with a pre-existing bank of messages for weekly, theory-based content (see Table 1) and an established timeline of when to intervene (see Table 2), contact between the exercise counselor and user is as simple as choosing a situation-specific message and further specifying details based on the individual.

This study is not without limitations. Given the nature of this investigation acting as a pilot trial, and in working with an entrepreneurial developer, a power calculation was not performed out of logistics in working with our industry partner and recruitment time constraints. Recruitment for this study was limited to one fitness facility due to restrictions placed by the app industry partner, resulting in limited power to detect group differences as well as an inability to conduct more complex analyses to better understand why potential differences existed (eg, mediation and multiple mediation). These findings may not be generalizable to individuals who are not able to afford fitness facility memberships; however, it should be noted that the facility utilized in this study offers subsidized memberships based on gross income. Given the general recruitment criteria (ie, 19-70 years of age, access to a mobile

phone device), the heterogeneity of our sample may have weakened our ability to draw concise conclusions and apply them to the general population as not all participants were new to exercise and may have had prior experience with mHealth app technology. Self-monitoring behavior was the secondary focus of this intervention. While app users' self-monitoring frequency was calculated using data from the app, the self-monitoring frequency of participants in the control condition (ie, no app) was based on self-report data, as the control aspect of this study design prohibited measurement via an app of these participants. The use of self-report data is inherent to recall bias [36], potentially resulting in unreliable results in the comparison of conditions. Lastly, this study looked at changes in exercise behavior over the duration of an 8-week intervention. As 40-65% of new exercisers drop out within the first 6 months [4] of a new program, an extended trial of the app is warranted to draw conclusions on long-term efficacy.

Future Directions

Wearable devices (eg, fitness trackers, pedometers, and accelerometers) have become sophisticated, with continued development of technology bringing credibility to such devices. Continued research on the development of mHealth devices could help to establish users' trust in the integration of technology (eg, mobile phone apps and wearable devices) to monitor health behaviors. Overall, an enhanced trust in the use of technology could have a meaningful effect on the ability of a device to impact the health of the public in general, as well as specialized populations [39]. Future studies should look to the integration of a true control group with access to a general health-related self-monitoring app, and objectively measure self-monitoring in the control condition, to provide further understanding of the mechanism under which users are affected by mHealth technology.

Conclusions

A total of 8 weeks of mHealth app use resulted in increased exercise and self-monitoring behavior, providing some support for the use of a self-monitoring app to increase adherence to exercise and self-monitoring of exercise behavior. This study protocol also demonstrates the feasibility of incorporating theory-based messages into existing mHealth apps, although the inclusion of such content did not lead to anticipated changes in self-efficacy to self-monitor or self-management of exercise behavior. Multiple inoculations of theory-based messages may be needed for sizable changes to be made in these constructs. Future research is warranted to understand the long-term efficacy of an mHealth app and its effect on exercise and self-monitoring behavior.

Authors' Contributions

The study idea was conceived by ECV and MEJ. ECV was responsible for the collection of data, performing data analysis and interpretation, and the writing and editing of the manuscript. MEJ was responsible for overseeing all aspects of the study, working with the industry mHealth app development team, contributing to data interpretation, and editing of the manuscript. NDO assisted with conceptualization of the study idea and review of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ANOVA: analysis of variance
BMI: body mass index
GLTEQ: Godin Leisure Time Exercise Questionnaire
HEART: Heart Exercise And Remote Technologies
SESM: self-efficacy to self-monitor
SMART: specific, measureable, attainable, relevant, and time-bound
SMS: short message service

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Original Paper

Cardiorespiratory Improvements Achieved by American College of Sports Medicine's Exercise Prescription Implemented on a Mobile App

Gianluca Rospo[1], MSc; Viola Valsecchi[1], MSc; Alberto G Bonomi[2], PhD; Inge WJ Thomassen[3], MSc; Saskia van Dantzig[2], PhD; Antonio La Torre[1]; Francesco Sartor[2], PhD

[1]Universita' degli Studi di Milano, Milan, Italy

[2]Philips Research, Eindhoven, Netherlands

[3]Technische Universiteit Eindhoven, Eindhoven, Netherlands

Corresponding Author:
Francesco Sartor, PhD
Philips Research
HTC34
Eindhoven,
Netherlands
Phone: 31 61550962
Fax: 31 402746321
Email: francesco.sartor@philips.com

Abstract

Background: Strong evidence shows that an increase in cardiorespiratory fitness (CRF) and physical activity (PA) reduces cardiovascular disease risk.

Objective: To test whether a scientifically endorsed program to increase CRF and PA, implemented on an easy-to-use, always-accessible mobile app would be effective in improving CRF.

Methods: Of 63 healthy volunteers participating, 18 tested the user interface of the Cardio-Fitness App (CF-App); and 45 underwent a 2-week intervention period, of whom 33 eventually concluded it. These were assigned into three groups. The Step-based App (Step-App) group (n=8), followed 10,000 steps/day prescription, the CF-App group (n=13), and the Supervised Cardio-Fitness (Super-CF) group (n=12), both followed a heart rate (HR)-based program according to American College of Sports Medicine (ACSM) guidelines, but either implemented on the app, or at the gym, respectively. Participants were tested for CRF, PA, resting systolic and diastolic blood pressures (SBP, DBP), resting, exercise, and recovery HR.

Results: CRF increased in all groups (+4.9%; $P<.001$). SBP decreased in all groups (-2.6 mm Hg; $P=.03$). DBP decrease was higher in the Super-CF group (-3.5 mm Hg) than in the Step-App group (-2.1 mm Hg; $P<.001$). Posttest exercise HR decreased in all groups (-3.4 bpm; $P=.02$). Posttest recovery HR was lower in the Super-CF group (-10.1 bpm) than in the other two groups (CF-App: -4.9 bpm, Step-App: -3.3 bpm; $P<.001$). The CF-App group, however, achieved these improvements with more training heart beats ($P<.01$).

Conclusions: A 10,000 steps/day target-based app improved CRF similar to an ACSM guideline-based program whether it was implemented on a mobile app or in supervised gym sessions.

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KEYWORDS

cardio-respiratory fitness; ACSM guidelines; physical activity; mobile app

Introduction

Low cardiorespiratory fitness (CRF) and physical activity (PA) have been shown to be two key independent risk factors for cardiovascular disease (CVD) and all-cause mortality [1-4]. These two are causally interconnected, although partially distinct [3]. High CRF is associated with higher habitual PA levels [5], and habitual PA seems to be the most important contributor to CRF [3,6]. Therefore, both CRF and PA should be fundamental

elements of any health intervention program, along with other crucial elements, such as diet and smoke cessation.

Ten thousand steps a day is a well-accepted PA goal, which has shown benefits in improving people's cardiovascular health [7]. The sustainability of a 10,000 steps/day target was evaluated in the whole Flemish community with a 1.5-year follow-up, showing an implementation rate of 58% among all contacted organizations, and that citizens aware of the 10,000 steps/day program were on average more active than those unaware [8]. As for other behavioral change programs, the likelihood of meeting the 10,000 steps/day goal depends also upon the intention to change and self-efficacy [9]. Yet, a program based on step counting, when the target is personalized rather than a fixed number for all subpopulations, would have the advantage to be compatible "with public health recognition that some physical activity is better than none" [10]. Although this is a very clear and straightforward goal, rather easy to implement in the general population, a PA program based exclusively on step counting does not necessarily have to be the most efficient program to improve people's cardiovascular health [11]. As pointed out by Tudor-Locke et al [10] 10,000 steps/day would be adequate for some people to accumulate 30 minutes of moderate to vigorous PA a day, and for others this would not be the case. Accordingly, the American College of Sports Medicine (ACSM) guidelines emphasize to engage in moderate and vigorous exercise intensity [5] in order to improve CRF. Training programs in line with these recommendations are usually designed based on target heart rate (HR), as a percentage of maximal HR or heart rate reserve (HRR) [5]. The efficacy of these new ACSM's guidelines accounting for exercise intensity was confirmed by several investigations [12-14]. In particular, Huang et al [12] and Swain [14] identified moderate intensity from 66% to 73% HRR, 40 to 50 minutes per session, 3 to 4 times per week, for 9 months, optimal to improve CRF in healthy sedentary adults and safer than vigorous intensity exercise. Schoenbron et al [13] brought direct evidence that adhering to the 2008 PA guidelines was associated with a reduction in all-cause mortality. Nevertheless, HR-based programs may result less straightforward to implement in the general and patient population, because of issues such as, chronotropic incompetence, and HR-lowering medications, inaccurate prediction of maximal HR [15]; and more difficult to understand than number of steps/day [16].

Next, to the issue of what is the most effective training program to reduce CVDs risk, there is the problem of getting people to adhere to such a program. Low adherence to PA and exercise programs has been a known issue for decades [17]. Many people do not manage to make regular use of health clubs for various reasons, among which are distance and perceived lack of time. Indeed, health clubs subscribers are known to overestimate their future attendance [18]. Some independent predictors of adherence such as demographic, and general health are particularly hard to address [17,19]. However, some other common barriers such as program-related factors (eg, lack of personalization), [17,20] and environmental factors (eg, find the time and place) [17,21] could be addressed by an appropriate lifestyle proposition.

Recently, smart, wearable, and mobile technology has enabled a large number of health applications [22]. As it was indicated in a recent systematic review, smartphones are more and more often used to measure and promote PA; however, currently still with modest results [23]. It has been shown that Web-based apps to improve and self-monitor PA were well received by middle aged men as long as the information was delivered quickly and it was easy to use [24]. As a confirmation of this, connected monitoring tools, such as smartphones, pedometers, and blood pressure devices used to support an exercise intervention could be overwhelming to users if those are asked to process too much information [25].

Knight et al [22] reviewed 379 PA apps, finding that none of those apps included public health recommendations for aerobic physical activity. The use of smartphones presents an important opportunity in rolling out an endorsed program aimed at improving CRF, because of the numerous possibilities that these platforms can enable, such as, to give real-time feedback on people's progress, to flexibly fit in people's daily schedule, and to connect with social networks allowing for social support.

Therefore, the primary aim of this study was to test whether a scientifically endorsed program to increase CRF implemented in an easy to use, and always-accessible mobile app, would be effective in improving CRF. A secondary objective of this study was to investigate how a HR-based training would compare with a steps-based training in terms of CRF changes.

Methods

Participants and Study Design

In order to test our research hypotheses a three group, pre- and posttest, 2-week intervention study was designed. The study protocol was approved by the Internal Committee of Biomedical Experiments of Philips Research as well as the Departmental Ethics Committee of the Milan University according to the Declaration of Helsinki.

Sixty-three participants were included in this study. Eighteen took part in a user experience test of the app. Forty-five participants took part in the actual experimental intervention protocol. Those participants were recruited via posters and at the local health center. After first interest in the study, volunteers were informed about the study protocol via information letters, where inclusion and exclusion criteria were already mentioned. These criteria specified, among others, the absence of chronic health conditions, no cognitive impairments, a low cardiorespiratory fitness (<45 mL/kg/min), an age ranged between 20 and 55 years, and a body mass index (BMI) limit not exceeding 35 kg/m^2. After signing the informed consent participants were screened for cardiovascular risk using the American Heart Association/ACSM Health/Fitness Facility Preparticipation Screening Questionnaire [26] and for PA readiness by means of the Physical Activity Readiness Questionnaire [27]. Participants were also asked to fill in a nonexercise (N-Ex) aerobic capacity questionnaire [28] to roughly estimate their initial fitness level. Self-efficacy to adhere to an exercise routine was evaluated via Bandura's questionnaire [29].

The latter 45 participants were assigned into three groups: the Step Count App group (Step-App) (n=16), the Cardio Fitness App group (CF-App) (n=17), and the Supervised Cardio Fitness group (Super-CF) (n=12). For logistic reasons only two groups, the Step-App group and the CF-App group, could be randomized. This is because the participants included in the Super-CF group, which was included as a training intervention quality check, had to be living in the vicinity of the fitness center used for the supervised exercise intervention. This has resulted in an inhomogeneity at baseline between this group and the other two. Participant characteristics at baseline are reported in Table 1. After a baseline CRF evaluation, 10 participants were excluded from the study because having a treadmill test estimated VO_2 max > 45 mL/kg/min (Figure 1).

Table 1. Participant characteristics.

	Step-App[a] group (n=8)	Super-CF[b] group (n=12)	CF-App[c] group(n=13)
	Mean ± standard deviation	Mean ± standard deviation	Mean ± standard deviation
Male/female	3/5	5/7	5/8
Age, years	40 ± 10	45 ± 3	42 ± 6
Height, m	1.69 ± 0.03	1.69 ± 0.12	1.71 ± 0.09
Weight, kg	68.20 ± 11.80	78.10 ± 19.10	81.60 ± 10.10
BMI, kg/m^2	23.70 ± 3.53	27 ± 4.70	26.60 ± 1.43
SBP[d], mm Hg	124 ± 11.60	132 ± 11.14	129 ± 16.80
DBP[e], mm Hg	76.90 ± 8.06[f]	87.40 ± 5.68[f]	83.70 ± 9.60
N-Ex[g] questionnaire	3.50 ± 2.27	0.58 ± 0.79	3.08 ± 2.27
Self-efficacy questionnaire[h]	57.70 ± 3.31	44.20 ± 9.60	61.60 ± 13.98
Estimated VO_2 max, mL/kg/min[i]	36.8 ± 4.90[j]	26.9 ± 5.60[j]	31.70 ± 6.40

[a]Step count app group.

[b]Supervised cardio fitness group.

[c]Cardio fitness app group.

[d]Systolic blood pressure.

[e]Diastolic blood pressure.

[f]Significant differences at the baseline between Step-App and Super-CF groups are $P<.01$.

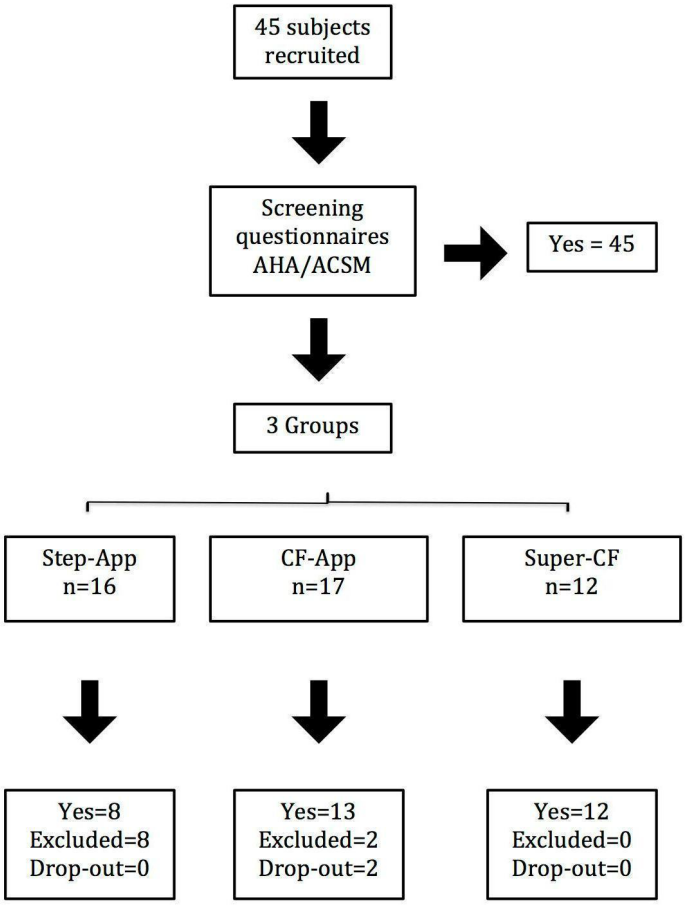
[g]Nonexercise aerobic capacity questionnaire (where 0 is inactive and 7 is very active).

[h]The self-efficacy questionnaire is on a 0 to 100 scale.

[i]Self-paced treadmill walk test was used to estimate VO_2 max.

[j]Significant differences at the baseline between Step-App and Super-CF groups are $P<0.05$.

Figure 1. Study enrollment flow-chart. Step-App, 10,000 steps/day training plan provided by a mobile app; CF-App, ACSM guidelines-based cardio-fitness training plan provided by a mobile app; Super-CF, ACSM guidelines-based cardio-fitness training plan provided by a personal trainer.



Testing Sessions

Participants were asked to visit our laboratories on three different occasions; for the baseline tests, the pretests, which occurred 1 week after the baseline tests, and the posttests, which took place immediately after the 2-week intervention. The design of the study is depicted in Figure 2. In order to characterize the population tested in this study and to confirm the self-reported inclusion parameters, height and weight, and therefore BMI, resting blood pressure and CRF were assessed. After the anthropometric measurements participants were asked to wear a HR chest strap monitoring device throughout the entire testing session. The resting HR was recorded while the participant was seated in a quiet and dimmed light environment for 3 minutes. At the end of this period the resting blood pressure was measured.

Two submaximal exercise tests were then conducted. The Ruffier-Dickson squat test [30] and the Ebbeling single-stage treadmill walk test [31]. The Ruffier-Dickson squat test consisted of a 45- second paced (40 bends/min) squatting exercise, followed by a 3-minute recovery period. Parameters evaluated were resting HR prior to the squatting exercise, HR at the end of the exercise, and recovery HR after 1 and 3 minutes. Moreover, the Ruffier-Dickson Index (RDI) was calculated according to the following equation:

$$RDI=(P_1-70)+2(P_2-P_0)/10 \quad (1)$$

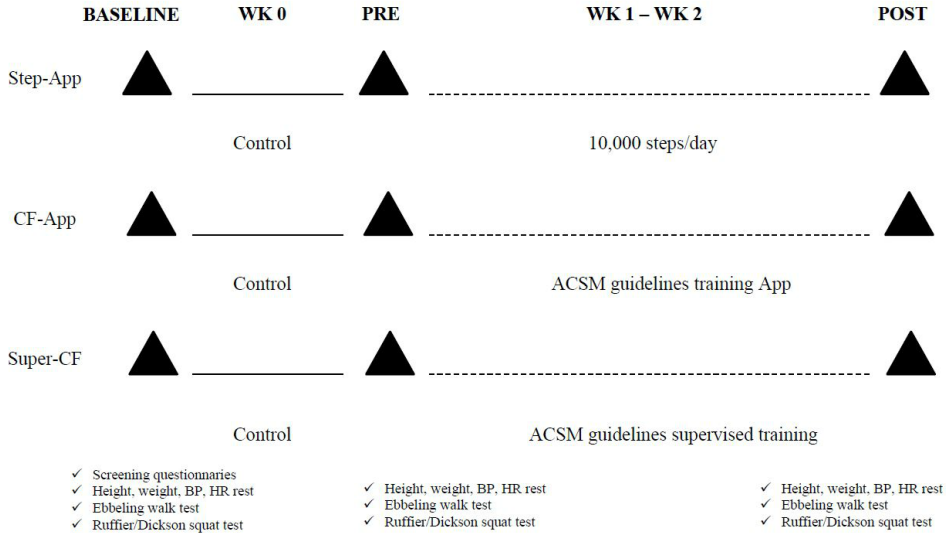
where P_0 is 15-seconds mean resting HR, P_1 is the maximum HR recorded during the first 15 seconds of recovery, and P_2 is the 15-seconds mean after the first minute of recovery (the period from 1 minute and 00 seconds to 1 minute and 15 seconds) [30].

The Ebbeling test consisted of a 4-minute walking session at an adequate speed so that the participant's HR would be between 50% and 75% of the estimated max HR (220 minus Age), followed by a 4 to 5 minutes session at a 5% incline at the same speed [31]. If HR between the seventh and the eighth minute did not differ more than 6 bpm, the test was ended, otherwise the test was continued for 1 more minute. VO_2 max was estimated according to the following equation:

$$VO_2 \text{ max}=15.1+(21.8 \cdot \text{Speed})-(0.327 \cdot \text{HR})-(0.263 \cdot \text{Speed} \cdot \text{Age})+(0.00504 \cdot \text{HR} \cdot \text{Age})+(5.98 \cdot \text{Gender}) \quad (2)$$

where treadmill speed was in miles per hour, HR in beats per minute, age in years, and gender was 0 for females and 1 for males. Except for the screening questionnaires and the height measurement, all other physical tests performed at baseline, were being repeated at pretest and after the 2-week intervention.

Figure 2. Study protocol outline.



Training Programs

Throughout the entire study period participants were asked to wear two HR monitors, a chest strap–based one, the same as mentioned above, and a wrist mounted optical sensor, validated by Valenti and Westerterp [32], which was able to send second by second HR data to a smartphone via Bluetooth connection. The smartphones were provided by the research team for the entire duration of the study. Participants' steps were assessed by a pedometer. This was clipped to the right pocket of the trousers or in absence of such pockets to the waist belt. All monitoring devices were taken off during the night and when the participants were showering or taking a bath.

During the pretest visit, participants received instructions about the training that they would follow during the two intervention weeks. The Step-App group was asked to complete 10,000 steps per day. Participants could access feedback on their progress via the device and via a standard mobile app, only during week 1 and 2, and not during the control week. No specific instructions were given to this group on how to achieve their goal. The pedometer has a display were steps could be read upon request, and it can be synchronized via Bluetooth connection directly with its dedicated mobile app. The Fitbit app did not provide any strategy on how to achieve the 10,000 steps/day target neither gave reminders.

The CF-App and Super-CF groups were asked to follow an intensity training based on the guidelines of the ACSM [5]. The main difference between these two groups was that the CF-App group received feedback on their progress via our CF-App (Figure 3), whereas the Super-CF group was asked to attend training sessions three or four times a week, depending on their starting CRF level, and received personal feedback only during those supervised sessions.

The training programs for the CF-App and the Super-CF groups were designed according to the recommended frequency, intensity, time, and type framework outlined in Table 7.4 of the ACSM's guidelines for exercise testing prescription consistent with the United States Department of Health and Human Services Physical Activity Guidelines for Americans [5]. Physical fitness classification was done according to Table 4.8 of the above mentioned ACSM's guidelines [5]. Because the guidelines provide ranges for frequency, intensity, and duration, we have selected the minimum value of the range as a guideline on which to give feedback.

For the CF-App group, the daily training target was visualized based on the concept of the Training Impulse method by Banister and Calvert [33]. The idea behind this visualization was to have a simple metric similar to steps per day that the participants could immediately understand.

This training monitoring metric was called "mBeats" and consisted of the number of heart beats in a personalized heart rate zone. This mBeats score was calculated over the week as target HR (bpm) × session duration (minutes) × the training frequency. Target HR was defined according to Box 7.2 of the ACSM guidelines [5], that is,

$$\text{Target HR}=[(HR_{max}–HR_{rest})] \cdot \%\text{intensity desired}]+HR_{rest} \quad (3)$$

where the desired intensity is determined according to the baseline fitness level, corrected for age and gender. For instance participants with a target HR=120 bpm (eg, 30% of HRR) and classified as sedentary would receive a training frequency of three times a week, and a training session duration of 30 minutes, making a weekly mBeats target equal to target HR × session duration × frequency per week of 10,800 mBeats. The week was divided into training days and resting days. In this example, a training day would have a daily target of 3600 mBeats, while a resting day would have a target of 0 mBeats. The daily targets are not fixed, but depend on the remaining mBeats for the week. In other words, if the weekly target mBeats was 10,800 and on the first training day 7000 mBeats were already achieved, the daily target on the second training day

would have been 1900 mBeats (the remaining 3800 mBeats divided by 2 remaining training days of the week).

The participants in the Super-CF group were instructed to visit the gym three to four times per week according to their training program consistent with the ACSM guidelines described above. During the training session at the fitness center participants were supervised and motivated by an experienced personal trainer. They were also asked to wear the HR monitors and step counters for the whole day during the entire intervention period without a specific goal.

Figure 3. Multiple screenshots of the Cardio Fitness mobile app used in this study.

Cardio Fitness Mobile App and Its User Experience

A mobile app was specifically designed for the purpose of this study. Main features included in this first prototype of the CF-App were a HR feedback element, daily and weekly mBeats targets, an activity planner based on the theory of implementation intentions [34], and progress toward the mBeats targets. Each of the screens was designed using Adobe Illustrator CS6, taking the Philips Communication guidelines and the Apple Human Interface Guidelines into account. Intuitiveness of the interface was tested by paper prototyping. To increase intuitiveness and simplicity, the design of the app elements was derived from standard Apple iOS interface elements. The app was compatible with Apple iPhone 5, with a screen resolution of 3.5 inch; 960 × 640 pixels. The main screen of the app showed the training HR zone, current HR, target amount of mBeats for that day, and progress toward this target. The main screen also showed a button 'view mBeats history'. This button led to a weekly overview of the percentage of achieved mBeats per day and per week (Figure 3).

Our App included a planning option, in which the participants could decide how to distribute their training days according to their own private schedule (Figure 3). This planning option also forecasted the number of mBeats that would be achieved by following one's personal plan. This feature was intended to help the participants understand beforehand whether their plan would be sufficient to reach their mBeats target. The CF-App was flexible to plan changes allowing the user to collect bonus points (ie, mBeats) during a resting day (Figure 3). Finally, the home screen of the app showed the current HR and whether this would be in the mBeats zone; the goal was displayed in a very simple fashion as an odometer, where achieved mBeats as a proportion of the day target was visualized in a filling ring (Figure 3). The participants in the CF-App group were instructed how to use the CF-App during the second visit (pretest).

User Experience Pilot Test

User interaction experience was tested during a 3-week pilot test by 18 healthy adults (age: 26-50 years, BMI: 18-25 kg/m2). The test started with a baseline week followed by two intervention weeks. During the baseline week, participants were instructed to wear the HR monitor and keep the app running, in order to collect physical activity data. All functionalities of the app were disabled and participants were asked to be as physically active as usual. After the baseline week, the 2-week intervention period started in which participants were coached to achieve their daily and weekly mBeats targets. At the end of the study, a one-on-one, semistructured interview was conducted to discuss usability and user experiences in depth. In addition, usability was measured with the Computer System Usability Questionnaire (CSUQ) [35]. This questionnaire consists of 19 items, categorized into three variables; system usefulness (items 1-8), information quality (items 9-15), and interface quality (items 16-19). In addition, an overall usability score is computed-based on all items.

Statistical Analysis

The Statistical analysis was performed using the Statistical Package for Social Sciences (version 21) and the level of statistical significance was set at 0.05. Data were presented as means ± standard deviations unless otherwise indicated. Dependent variables were analyzed with a two-way, repeated, measures-mixed analysis of the variance (ANOVA), where the two factors were: time (pre- and post-intervention) and group (Step-App, CF-App, Super-CF). Because only the Step-App and the CF-App groups were randomized, a two-way, repeated measures ANOVA was performed also only on those two groups. If there had been violations of the sphericity, the corrections of Green-house Geisser if <0.75 and Huynh-Feldt if >0.75 were applied. The significant interactions were followed by post-hoc Tukey test. Pearson correlation coefficients were calculated between RDI and estimated VO_2 max.

Results

Cardio-Fitness App Usability

Overall, participants were very positive about the potential of the CF-App and the concept of collecting heart beats to increase PA. Nonetheless, the pilot test revealed some points for improvement for the app. Most participants stated that their target zone was too narrow, and for some participants the zone was too high. Based on this feedback, the target HR zone was widened in the intervention study. Moreover, more features and functionality could be added to make the CF-App useful for people with various health goals. The current app is specifically designed to improve CRF, but over half of the participants stated they would want more information about the effects of all activities, including activities that are in a different HR zone. Furthermore, they wanted to be able to set their own exercise goals, to, for example, maintaining health or losing weight.

Other than many other popular fitness apps, the CF-App stimulates users to achieve a weekly exercise target, rather than daily targets. The majority of participants (15/18, 83%) were in favor of a weekly target, as opposed to a daily target, because the amount of exercise they do is not the same for every day, but is fairly similar every week. Five of them stated that although they preferred a weekly target, they would be okay with having a daily target, as long as the daily target is integrated with what they have planned in their activity planner. Only three participants were in favor of the daily target because it would motivate them to get enough exercise on a daily basis. Overall usability from the CSUQ was toward the positive end of the scale. On a scale from 1 to 7, the participants rated usability 4.46 ± 1.46, quality of the interface 4.96 ± 1.26, system usefulness 4.72 ± 1.34, and information quality 4.21 ± 1.28.

The ratings on the CSUQ questionnaire were in line with the qualitative findings obtained during the interviews. Ratings on the three variables were on the positive side of the scale, confirming the potential of the app. However, with an average rating of 4.5 on a 7-point scale, usability is not rated extremely high. This can mostly be accounted to some technical issues and the limited functionality of our first prototype. Moreover, participants identified missing elements that would make the app better, more interesting, and easier to interpret. Half of the participants explicitly stated they would add more parameters, such as speed and distance. This would make it easier for them to relate the mBeats to something they are already familiar with. Ten participants would like to add global positioning system tracking, or at least link the timestamps in the history view to a location, because it could give them insight in the effects of certain routes on their exercise performance.

A majority of the participants mentioned that they would like advisory or motivational messages in the app. These could be tips on what kind of activities they could do to reach their target (8 participants), or information on how they are doing during exercising (6 participants). In addition, six participants mentioned they want to get messages about their achievements so far, like how many beats they still need to achieve, and another six participants wanted motivational messages such as ‘good job’ or ‘you have been idle for a while, isn’t it getting time to go for a jog?’

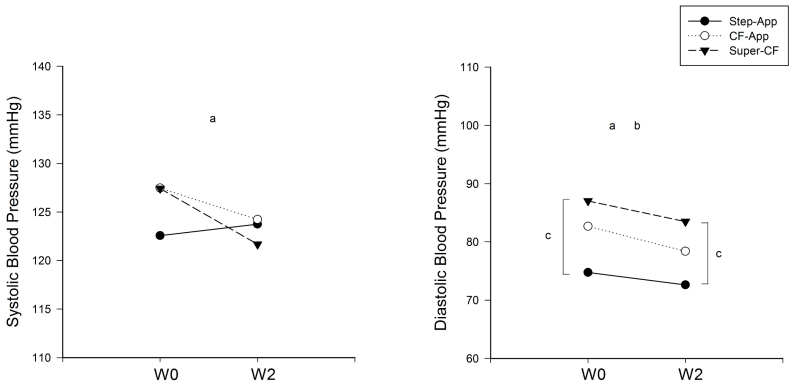
Some participants did not fully understand the mBeats concept. They would need more education on advantages of the concept and measuring heart rate. Furthermore, they would need support in interpreting their data, to gain better understanding of their performance.

Because people were uncertain about their current level of fitness and how to improve or maintain it, they would want the app to objectively assess their current fitness level and use this information to create a personalized training program, with feasible goals and reliable, and accurate HR zones.

Weight and Blood Pressure

There were no significant time × group interactions ($F(1;30)=0.466$, $P=.63$), nor main effect of time ($F(1;30)=0.189$, $P=.67$) and of group ($F(1;30)=2.153$, $P=.13$) in body weight. No time × group interaction was present for systolic ($F(1;30)=2.169$, $P=.08$) and diastolic ($F(1;30)=0.426$, $P=.66$) blood pressure. Although, a significant main effect of time was observed in both systolic blood pressure (SBP) ($F(1;30)=4.946$, $P=.03$; Step-App: +1.19 mm Hg; CF-App: -3.23 mm Hg; Super-CF: -5.75 mm Hg) and diastolic blood pressure (DBP) ($F(1;30)=12.585$, $P<.001$; Step-App: -2.12 mm Hg; CF-App: -4.31 mm Hg; Super-CF: -3.54); only the DBP showed a significant main effect of group ($F(1;30)=5.765$, $P<.01$). Following-up these significant differences between groups it was observed that the DBP in the Step-App group was lower than in the Super-CF groups at baseline ($P<.01$) as well as at week 2 ($P<.001$) (Figure 4). When only Step-App and CF-App were compared, a main effect of group for body weight, CF-App being heavier ($F(1;19)=7.345$, $P<.05$), and a main effect of time for DBP ($F(1;19)=6.829$, $P<.05$) were found.

Figure 4. Baseline (W0) and 2 weeks (WL2) systolic and diastolic blood pressure changes induced by the interventions. Step-APP, 10,000 steps/day training plan provided by a smartphone application; CF-App, ACSM guidelines-based cardio-fitness training plan provided by a smartphone application; Super-CF, ACSM guidelines-based cardio-fitness training plan provided by a personal trainer. a, Significant main effect of time. b, Significant main effect of group. c, Significant difference between Step-App group and Super-CF group.



Estimated Maximal Oxygen Uptake, Step Counts, and mBeats

Maximal oxygen uptake estimated by the Ebbeling treadmill walk test did not show any significant time × group interaction (F(1;30)=0.543, *P*=.59). However, there were significant main effects of time (F(1;30)=17.451, *P*<.001) and of group (F(1;30)=5.380, *P*<.01). Although a significant main effect of time associated with positive deltas in all groups showed an overall improvement in CRF levels in all three groups (Step-App: +0.95 mL/kg/min; CF-App: +1.70 mL/kg/min; and Super-CF: +1.85 mL/kg/min), post-hoc analysis showed a significant difference between the Step-App group when compared with the Super-CF group (*P*<.001) (Figure 5 A).

A significant time × group interaction was found in week mean step counts (F(2;60)=4.903, *P*<.01). Follow-up analysis showed a significant difference at week 1 and 2 between CF-App and Super-CF group (*P*<.01 and *P*<.05) (Figure 5 B). In detail, the Step-App group had a baseline mean step count of 8512 steps/day, 9438 steps/day at week 1, and 9246 steps/day at week 2; the CF-App group: 6808 steps/day at baseline, 7534 steps/day at week 1; and 7775 steps/day at week 2; finally the Super-CF group had a baseline mean step count of 6479 steps/day, 10,005 steps/day at week 1; and 9763 steps/day at week 2. mBeats expressed as a percentage of the participants' weekly target showed a significant time × group interaction (F(3.231;48.463)=7.909, *P*<.001). Post-hoc analysis underlined significant differences between the Step-App group and the Super-CF group during week 1 (*P*=.045) and week 2 (*P*=.03) (Figure 5 C). When only Step-App and CF-App were compared just one significant interaction was found. This was for mBeats (F(1.580;30,019)=8.933, *P*<.001), showing a simple main effect of time in higher mBeats at week 1 and 2 in the CF-App (*P*<.001). There was a significant main effect of time in Ebbeling predicted CRF (F(1;19)=8.814, *P*<.001). Steps counts showed two trends, one of a main effect of time toward an increase (F(2;38)=2.994, *P*=.065) and the second one of a main effect of group (F(2;38)=3.998, *P*=.060), but no interaction.

Heart Rate Outputs and Ruffier-Dickson Index

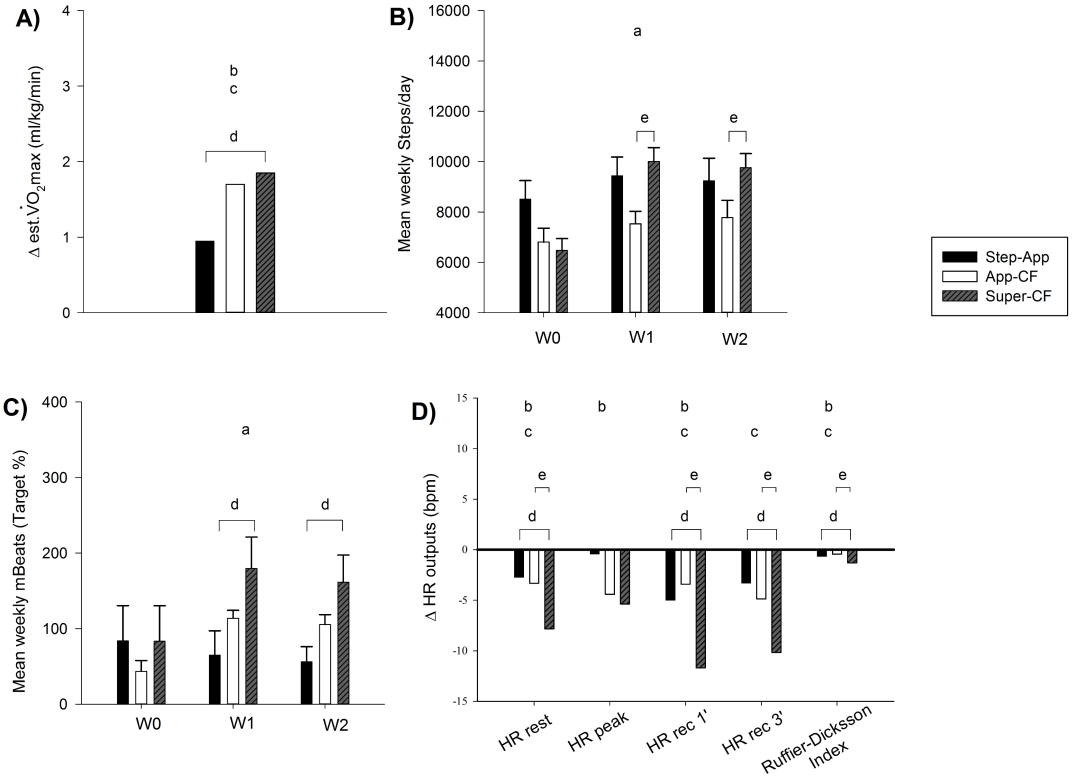
HR rest did not show a time × group interaction (F(1;30)=2.169, *P*=.13). However, main effects of time (F(1;30)=12.310, *P*<.001) and of group (F(1;30)=11.132, *P*<.001) were observed. In particular the post-pre HR rest difference was significantly lower (*P*<.001) in the Super-CF group (-7.84 bpm); compared with Step-App group (-2.74 bpm) and the CF-App group (-3.33 bpm) (Figure 5 D). The peak HR during the squat test showed no time × group interaction (F(1;30)=1.508, *P*=.36). However, there was a significant main effect of time (F(1;30)=6.201, *P*=.02) but not between groups (F(1;30)=1.683, *P*=.20). All three groups recorded lower HR peak due to the three different interventions (Step-App: 119.4 bpm; CF-App: 122.2 bpm; Super-CF: 127.7 bpm) (Figure 5 D).

HR recovery after 1 and 3 minutes did not show significant time × group interactions (F(1;30)=1.368, *P*=.27; F(1;30)=0.832, *P*=.49). HR measured after 1 minute revealed main effects within (F(1;30)=9.318, *P*<.01) and between groups (F(1;30)=16.798, *P*<.001). The Super-CF group had a significantly lower HR (-11.71 bpm) than both the Step-App (-5.01 bpm; *P*<.001) and the CF-App (-3.42 bpm; *P*<.001) groups. Also HR recovery measured after 3 minutes showed a main effect of group (F(1;30)=7.989, *P*<.001). After 3 minutes, the HR in the Super-CF group (-10.17 bpm) was significantly lower than the one in the Step-App (-3.31 bpm; *P*<.001) and the CF-App group (-4.87 bpm; *P*<.01). Conversely, no within group differences were observed (F(1;30)=1.634, *P*=.21).

In order to confirm the validity of the RDI as CRF index, we correlated it with VO_2 max estimated using baseline values. A negative significant correlation was present between RDI and the estimated VO_2 max (r=-0.46, *P*<.01). We then have used this as an additional marker of CRF. RDI did not show any time × group interaction (F(1;30)=1.148, *P*=.25), but significant main effects of time (F(1;30)=6.679, *P*=.02) and group (F(1;30)=3.374, *P*=.03). The RDI was significantly lower in the Super-CF group than the Step-App (*P*<.05) and the CF-App (*P*<.01) groups (Figure 5 D).

When only Step-App and CF-App were compared, only two significant main effects of time were found. One for HR after 1 (F(1;19)=4.619, *P*<.05) and the other for HR after 3 minutes (F(1;19)=4.289, *P*<.05).

Figure 5. A) VO_2 max week 2 – baseline deltas. B) Mean weekly steps showed for the baseline week 0 (W0), and the two intervention weeks, week 1 (W1), and week 2 (W2). C) Mean weekly mBeats expressed as percentage of target mBeats (for the definition of mBeats see methods section). D) Week 2 - baseline Heart rate (HR) deltas at rest, for the maximal recoded during a squat exercise test (peak), 1 and 3 minutes during the recovery from the squat exercise test, and for the Ruffier-Dickson Index as defined in the method section. a, Significant time x group interaction. b, Significant main effect of time. c, Significant main effect of group. d, Significant difference between Step-App group and Super-CF group. e, Significant difference between CF-App and Super-CF group.



Discussion

Principal Findings

Our research showed that a scientifically endorsed program to increase CRF, in line with ACSM's guidelines, implemented on smartphone in an easy to use and always-accessible app can improve fitness, and other health-related parameters. According to the treadmill walk test, CRF increased in all three groups not showing any interaction between the groups. Although, the weekly mean number of steps walked by the CF-App group did not increase drastically from baseline levels (6808 steps/day at baseline; 7534 steps/day week 1; and 7775 steps/day week 2), and it may seem that participants in the CF-App group were more efficient than those in the other two groups in improving their CRF levels; yet no interaction and no main effect of group were found between the Step-App and the CF-App groups indicating that steps/day did not differ that much among the two App groups. The mBeats for the CF-App group did increase significantly from 43.5% of the mBeats target at baseline, 113.7% at week 1 and 105.5% at week 2, whereas mBeats in the Step-App group did not increase (ie, 60% of the hypothetical target mBeats). Although the Super-CF group achieved a higher mBeats level (ie, approximately 170% of the target mBeats), the participants of this group have done that by walking the highest number of steps per day. Most probably because these participants trained at the gym under the supervision of a personal trainer, three to four times a week. These results seem to suggest that intensity as well as volume training delivered by means of an easy to use mobile app accessible at any time, may be an efficient alternative to attending fitness classes. Although programs targeting steps can be a useful tool for sedentary people with a very low CRF level [7], this may be inadequate for people with higher baseline PA levels and CRF; this is particularly true if stepping rate is not high enough (eg, >150 steps/min) [36].

Resting blood pressure results showed a small but significant decrease in SBP in the two intensity groups (CF-App and Super-CF), but not in the volume group (Step-App). DBP decreased in all three groups. Previous studies have found that both volume and intensity training are able to reduce blood pressure in hypertensive people [37]. It is important to point out that our sample was composed of normotensive individuals.

Resting as well as recovery HR did decrease, as expected [37], in all three groups because of both volume (ie, steps) and intensity (ie, HR) interventions. However, the Super-CF group showed the largest effect. Accordingly, peak heart rate during a squat test showed improvements mainly in the Super-CF groups.

Limitations

Our study had a number of limitations. Cardiorespiratory fitness was only indirectly estimated by using a treadmill submaximal test and a squat test [30,31]. The first has been shown to have high accuracy and repeatability [38], while the second was used

because it has the advantage not to require any specific laboratory equipment except for a HR monitor, a stopwatch, and a metronome. The latter two elements are easy to implement on a smartphone, which would make the squat test ideal for self-testing. The good correlation between the squat test and the treadmill test indicates that a squat-based self-assessment test could be implemented to such a CF-App, in order to track progress. This correlation also confirmed the evaluation of Sartor et al [38], whom suggested the use a squat test, for the home settings; still a further thorough validation of this test is required.

Conclusions

Our CF-App was built taking into consideration the user experience feedback. As shown in the Methods section an additional qualitative study was conducted on 18 people to improve the look and feel and the experience flow of our software app. Qualitative reports confirmed the high relevance and acceptance of our app. However, it could be improved by providing educational, interpretational, and motivational messages. Ultimately, it is important for people who have a low PA level and a low CRF to start doing something to improve their lifestyle behavior. Adhering one to one to guidelines and recommendations can be overwhelming for most people [17]. By implementing those guidelines in a portable device and providing straightforward feedback on daily as well as weekly progress, without penalizing users when goals are not strictly met, could be an interesting way forward in cardiorespiratory health promotion and CVD prevention. Step-counting–based PA programs are a good starting point for sedentary people as long as these are designed to incentivize a breaker pattern [39].

Another important aspect of our research was to encourage people to take any occasion throughout the day to engage in moderate to vigorous PA. For the less fit people this meant taking the stairs more often, cycling to work at a faster pace, or brisk walking during the lunch break instead of having a stroll. By no doubts motivation is key, and people with low readiness to change and self-efficacy will still struggle to adopt an active lifestyle. In the current study, given 100 as the maximal motivation to exercise, we had moderate levels in self-efficacy in all three groups, averaging approximately 54.3 ± 9.1. Yet all groups showed good short-term adherence throughout the two intervention weeks, still longer-term adherence, which is the hardest to achieve, remains to be investigated.

For logistics reasons, participants were not randomly assigned to the Super-CF group. This has resulted in a baseline difference in CRF. However, this group was mainly used as a quality check of the intervention, to control for the main effect of time. This study, as mentioned above, was also kept rather short, only 2 weeks of intervention. We have shown in the past that sedentary people can improve their CRF when undergoing a vigorous but short training program [40]. The choice to keep the study short was mainly dictated by the necessity to have high adherence to prove the principle that CRF can be modified by an unsupervised app-supported program. However, this did not enable us to investigate long-term adherence. Consequently, future studies should examine long-term adherence for such an app-based program and determine how to implement guidelines into flexible exercise prescription, which can be adapted according to users' needs, without jeopardizing effectiveness.

In conclusion, a 10,000 steps/day target-based app improved CRF similar to an ACSM guidelines-based program whether it was implemented on a mobile app or in supervised gym sessions. Moreover, HR-based training improved CRF in equal measure as a steps-based training, but with a higher number of heart beats in a training zone for a similar number of steps/day than a Step-based training.

Acknowledgments

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Conflicts of Interest

Francesco Sartor, Alberto G. Bonomi, and Saskia van Dantzig work for Royal Philips Electronics.

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Abbreviations

ACSM: American College of Sports Medicine
ANOVA: analysis of the variance
BMI: body mass index
CF-App: cardio-fitness app
CRF: cardiorespiratory fitness
CSUQ: computer system usability questionnaire
CVD: cardiovascular disease
DBP: diastolic blood pressures
HR: heart rate
HRR: heart rate reserve
PA: physical activity
RDI: Ruffier-Dickson index
Step-App: step-based app
Super-CF: Supervised Cardio-Fitness
SBP: systolic blood pressures

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Original Paper

Young People's Views and Experiences of a Mobile Phone Texting Intervention to Promote Safer Sex Behavior

Rebecca Sophia French[1], MSc, PhD; Ona McCarthy[2], MSc; Paula Baraitser[3], FFPH, FFSRH; Kaye Wellings[1], FFPH, FRCOG, FFSRH; Julia V Bailey[4], MBBS, MRCGP, MSc, PhD; Caroline Free[2], MBChB, MSc, PhD

[1]London School of Hygiene & Tropical Medicine, Department of Social & Environmental Health Research, London, United Kingdom

[2]London School of Hygiene & Tropical Medicine, Department for Population Health, London, United Kingdom

[3]Kings College London, Sexual Health Research Group, London, United Kingdom

[4]E-Health Unit, Research Department of Primary Care and Population Health, University College London, London, United Kingdom

Corresponding Author:
Rebecca Sophia French, MSc, PhD
London School of Hygiene & Tropical Medicine
Department of Social & Environmental Health Research
15-17 Tavistock Place
London, WC1H 9SH
United Kingdom
Phone: 44 (0)20 7927 2047
Fax: 44 (0)20 7927 2701
Email: Rebecca.French@lshtm.ac.uk

Abstract

Background: The risk of poor sexual health, including unplanned pregnancy and sexually transmitted infections (STIs), is greatest amongst young people. Innovative and acceptable interventions to improve sexual health are required. Mobile phone text messaging (short message service, SMS) interventions have the potential to reach large numbers of people at relatively low cost, but greater understanding is needed on how these interventions should be developed and how they work.

Objectives: The aim of this paper is to explore young people's views of and experiences with a mobile phone text messaging intervention to promote safer sex behavior.

Methods: We undertook qualitative interviews with young people aged 16 to 24 years as part of a pilot trial of a sexual health intervention delivered by text message in the United Kingdom. Study participants received sexual health promotion text messages based on behavior-change techniques. The message content, tailored by gender and STI status, included support for correct STI treatment and promotion of safer sex behaviors. Young people were eligible if they had received a positive chlamydia test or had more than one partner and at least one episode of unprotected sex in the last year. Telephone interviews were conducted 2 to 3 weeks after initiation of the intervention. A semi-structured topic guide was followed to explore participant experiences and a thematic analysis was conducted.

Results: We conducted 16 telephone interviews with participants who had received the text intervention and an additional four interviews with those in the control group (13 women and 7 men). Intervention participants found text messages easy to understand and appearing to come from a friendly and trustworthy source. They considered the frequency and timing of messages to be appropriate, and delivery via mobile phones convenient. Receipt of support by text message allowed recipients to assimilate information at their own pace, and prompted reflection on and sharing of messages with friends, family members, and partners, thus providing opportunities for education and discussion. For some recipients, the messages had increased their knowledge of how to correctly use condoms. Some described how the messages had increased their confidence and reduced stigma, enabling them to disclose infection to a partner and/or to do so sooner and more calmly. Discussing the messages with a partner reportedly enabled some women to negotiate condom use.

Conclusion: From the perspective of the recipients, the tone, frequency, and content of the text messaging-based sexual health intervention was acceptable and appropriate. Their accounts indicated that the intervention increased knowledge, confidence, and safer sex behaviors. A large-scale randomized controlled trial (RCT) is needed to assess effectiveness.

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KEYWORDS

text messaging; young people; sexual health; intervention; qualitative interviews; sexual behavior; behavior change

Introduction

Globally, unsafe sex is one of the main risk factors in young people aged 10 to 24 years [1]. In Britain, young people are at greater risk of poor sexual health outcomes compared to older-age groups. Men and women aged 16 to 24 years are more likely to report at least two sexual partners in the last year with whom no condom was used [2], pregnancies in under 20 year old women are more likely to be unplanned [3], and the prevalence of chlamydia infection peaks in the late teenage years and early twenties [4]. Accordingly, most prevention efforts target men and women less than 25 years.

The Department of Health has prioritized improving sexual health in young people, yet evidence of the effectiveness of behavioral interventions using traditional methods to improve sexual health status to achieve this goal has, to date, been partial and equivocal [5,6]. Interventions that are cost-effective and broad-reaching are needed [7]. Interventions delivered by mobile phones have the potential to reach large numbers of people at relatively low-cost, and have been effective in changing some health behaviors [8]. In the United Kingdom, nine in ten young people aged between 16 to 24 years sent text messages on a daily basis to communicate with family and friends [9]. Mobile phones can provide the private, confidential, and non-judgmental support essential to a sexual health intervention targeting young people [10]. In addition, support can be delivered at any time, in any location, whenever it is needed. Behavior change techniques used in effective face-to-face interventions can be modified for delivery via text message [8].

The effects of text messaging (short message service, SMS) on key safer sex behaviors, including telling your partner about a sexually transmitted infection (STI), correctly following treatment advice, obtaining STI testing for yourself and your partner prior to unprotected sex and condom use, has not been reliably established. A systematic review of randomized controlled trials (RCTs) of mobile technology-based interventions designed to improve health or health care services identified three trials employing text messages designed to improve sexual health [11]. One trial reported increases in discussing sexual health with health professionals and improvements in STI testing and treatment; however all three trials had a high or unclear risk of bias and/or were underpowered to detect effects [12-14]. A systematic review of sexual health education delivered via social media or text message to adolescents and young adults identified five studies using text messages, three of these using a RCT design [15]. An increase in sexual health knowledge amongst those exposed to the intervention was observed in all these trials [12,16,17]. While some positive effects on behavior were observed, including increased condom use, improvement of STI screening, and a decline in multiple partners, results were not consistent across these studies. In addition, limitations included small sample size, short-term follow up, reliance on self-reported data, and poor retention.

We developed a text message-based intervention designed to promote safer sex behaviors, such as correct and consistent condom use, informing partners about STIs, and testing for STIs prior to unprotected sex with a new partner [18]. The intervention employed educational, enabling, and incentivizing behavior change functions and identified the following twelve behavior change techniques in effective face-to-face safer sex interventions: (1) information about health consequences of behavior, (2) instruction on how to carry out the behavior, (3) demonstrations of risk reduction behavior, (4) social support, (5) emotional support, (6) social rewards, (7) non-specific incentives, (8) encouragement to add objects to the environment, (9) anticipated regret, (10) problem solving, (11) action planning techniques, and (12) reframing [19-21]. Barriers to safer sex behaviors were identified from the scientific literature and functions and techniques selected to address these [21]. Messages were generated by user and expert views and refined based on feedback from potential users from eight focus groups, a survey of 100 respondents, and eight telephone interviews following receipt of the prototype messages.

The qualitative study reported here was part of a pilot RCT to establish the feasibility of a main trial to determine the effects of the intervention on safer sex behaviors. Young people aged 16-24 years were eligible if they had been diagnosed with a chlamydia infection or had more than one partner and at least one occasion of unprotected sex (ie, sex without a condom) in the last year. Participants were recruited from sexual health clinics in urban and rural areas in England. All received usual care in accordance with standards set by the British Association of Sexual Health and HIV (including treatment and support with partner notification if appropriate), and they were free to seek any other support. Participants were randomly allocated using a remote computer-generated allocation to receive either the sexual health text message intervention or the control text messages. The intervention content included messages that support correct STI treatment (taking the treatment, informing partners of the infection, abstaining from sex for one week after you and your partners are treated), and promote safer sex behaviors. Some examples of the texts are provided in Textbox 1. The messages are grounded in behavior change theory and are tailored according to gender and infection status at enrolment. The pronouns used are appropriate or the messages are gender-neutral. Some messages were only sent to some groups. For example, in focus groups women reported that they valued messages regarding how other women negotiated condom use whilst heterosexual men reported messages about how condom negotiation were not relevant to them, so they were not sent those messages. Participants who were diagnosed with an STI at enrolment were sent messages relating to correct treatment and partner notification. Participants could request further texts on a topic, for example, how to avoid condom problems or to receive tips from others. Web links to Brook (a young people's sexual and reproductive health provider) and NHS choices (run by the National Health Service) were also provided for further information.

The frequency of messages was most intensive in the first week of the intervention, with participants receiving between 7-17 messages (varying by gender and infection status). Frequency declined over the course of the intervention and by month 12, participants received only one message per month (Multimedia Appendix 1). The control content included messages about the importance of taking part in the trial and did not include information about safer sex or behavior change. Messages were sent automatically to participants' mobile phone.

Textbox 1. Examples of control and intervention text messages.

Text messages

- Intervention
  - Treatment, informing partners, and adherence
    - Most people who have an infection don't know. Your partner(s) could be infected so it's important to tell them that they need treatment too.
    - "I talked to my friend and it turned out she'd had it. And so had quite a few others I knew." Text 2 to hear more.
  - Safer sex behavior support
    - Think back to a time (or times) when you had sex without a condom. Ask yourself how you could you do things differently next time.
    - If you're new to condoms, using them can be tricky at first but it gets a lot easier with practice. Visit LINK for tips on how to use them.
- Control
  - Your participation in the texting study will help us understand more about what kind of help will improve young people's sexual health.

Methods

Recruitment

The study coordinator (OM) telephoned pilot trial participants who expressed willingness to participate in the interview study at enrolment. Interview participants were selected from two of the study sites, London (coded ID01) or Cambridgeshire (ID03), to ensure representation from inner-city and suburban or rural settings. Participants were purposively sampled to ensure variation according to age, gender, STI test result at enrolment, and whether they had been allocated to the intervention or control group. Control group participants were included as we wanted to explore young people's experiences of participation in the pilot trial. Potential interviewees were given verbal and written information about the study. Informed written consent was obtained either by email or text message [22].

Interviews

RF conducted qualitative interviews with participants by telephone 2-3 weeks after enrolment to the pilot trial. One interview was conducted by OM. Interviews took place between October 2013 and January 2014. The interviews followed a semi-structured topic guide which aimed to find out about participants' views, experiences, and recommendations for improvements to the intervention (Multimedia Appendix 2). Questions were included on tone and frequency of text messages, views regarding the message content, any concerns about others viewing texts, what (if anything) they had learned from the texts, sexual behavior since enrolment (such as condom use and partner notification), and suggested improvements to the intervention. All interviewees were asked about experiences of being in the study, including why they agreed to participate, how they were enrolled, and their views on the randomization process and follow-up procedures (these findings are not presented in this paper). Participants were each given £20 for completing the interview. The interviews were audio-recorded and transcribed verbatim.

Participants provided self-reported sexual behavioral data at baseline, 1, and 12 months. Follow-up chlamydia tests were obtained at 3 and 12 months, either via post or the designated sexual health service, whichever was most convenient to the participant.

The aim of this paper is to explore young people's initial views and experiences of the text message intervention.

Thematic Analysis

The software Nvivo 10 was used to manage data and to code transcripts thematically. After familiarization with data, RF generated an initial coding framework (with OM). RF coded all the interviews according to the framework and these were checked by and agreed with CF. Each theme was described and sub-themes identified by RF and CF. RF searched for deviant or atypical cases.

Results

A total of 16 interviews were conducted with young people allocated to the intervention group. A further 4 interviews were conducted with young people in the control group. None of those contacted declined to be interviewed. One participant who agreed to be interviewed did not answer calls at the pre-arranged interview time. The characteristics of participants are shown in Table 1. Of the participants, 7 females (5 in the intervention group) and 4 males (2 in the intervention group) were diagnosed with a chlamydia infection at enrolment. Another male participant in the intervention group was diagnosed with gonorrhea at enrolment.

Table 1. Participant characteristics (N=20).

Age group		London (ID01)		Cambridgeshire (ID03)	
		Male, n	Female, n	Male, n	Female, n
16-18 years					
	Intervention	2	1	0	2
	Control	0	0	0	1
19-21 years					
	Intervention	2	3	0	2
	Control	0	0	1	1
22-24 years					
	Intervention	0	2	1	1
	Control	1	0	0	0

Engagement With Intervention Text Messages

Most young people were positive about the intervention. The five key themes relating to user engagement with the text messages identified are (1) the importance of tone; (2) frequency and timing of texts; (3) convenience; (4) saving messages; and (5) the sharing of messages.

Tone

Most participants said that messages sounded as if they were coming from a friendly, trustworthy source and they liked that the messages were simple, avoided slang, and were not too long.

> *They didn't use like too many big words. If it had been a load of words that I didn't really know what they meant I'd have probably not read like the first one and then I'd have probably not read any of the others after that.* [ID030012, M, 24, Intervention, chlamydia positive]

Some described how it was important for them to relate to and trust the messages. They did not feel pressured, told-off, or lectured; the messages were "on their side" and enabling.

> *It was kind of like coming from a friend 'cos it's like it's not speaking down to you, it's like speaking to you. They're like not trying to make you feel like little, they're trying to like help you kind of thing.* [ID03003, F, 19, Intervention, chlamydia positive]

> *I didn't feel like I was pressured into it. It was my choice if I wanted to either carry on doing the text message, if I wanted to find out the stories (links to messages on how others managed a problem or situation, see Box 1). It was very friendly, very user-friendly.* [ID03002, F, 21, Intervention, chlamydia positive]

One 21 year old man who had previously had genital warts felt the messages were "patronizing and dumbed-down". He said he would have preferred more statistical facts.

Frequency and Timing

All the participants thought the frequency of the texts, one or two a day, was just right. Their view was that they would have felt bombarded had there been any more, but less would not have been enough to reinforce the messages.

> *It's been really helpful … not too much, like they don't text too much and it gives you like information, like just little bits of information and it kind of sticks in your head so it's been good yeah."* [ID03006, F, 18, Intervention, chlamydia positive]

One participant was impressed that messages continued to arrive during the weekend. It was possible to request the time of day that messages would be sent; however, none of participants had chosen to do this but felt it was an important option. Some participants who were working or at college explained that receiving texts during the day was not problematic as they tended to leave their phones in their bags and would check messages at breaks. A few mentioned the merit in sending messages out on Friday evenings when young people may be going out drinking, for example, to remind them to carry condoms before going out.

Convenience

Delivery via mobile phones was felt to be appropriate for young people; *kids are always on the phone.* Participants described the convenience of receiving texts on their phones as they are easily accessible and did not take up much time or attention, unlike having to go somewhere after work or trying to read through pages on the Internet. For example, "...it's nothing like sitting on the Internet and reading all different things about it, just kind of getting some text messages every now and again" (ID03006, F, 18, Intervention, chlamydia positive). And, "'cos it's just a text, so even if you can't read it right then you'd go back to read it later, it doesn't cause any problems" (ID03013, F, 21, Intervention, chlamydia positive).

Saving Messages

Most intervention participants described having saved the messages they had received. Some said that they returned to the messages, prompting reflection, or kept them for future reference.

> *I've got all of them on my phone so like sometimes I'm going through my text messages… and then I go back through and read the stuff that's come through*

> *and I do find it very helpful... but sometimes you want to go back on stuff, … if you are thinking about where your situation's gonna be, you're meeting a new partner and you're like, right, we're gonna have to have this conversation,… then you have a look and then you kind of, it helps you, it builds your confidence a bit with the tips and it's the reassurance.* [ID03002, F, 21, Intervention, chlamydia positive]

The fact that the messages were not personal allayed fears connected to their discovery by other people. Phones of some participants' were locked and could not be accessed by anyone else and some set their phones to prevent messages popping up on the screen. A couple of participants deleted their messages, one saying that he had done this as he did not want anyone else coming across them.

Sharing Intervention Messages

Many participants described sharing the text messages they received. For some this was done to pass on information to younger siblings or friends. One young woman had kept her messages so that she could forward them to friends if they had any problems in the future. Another young woman in the control group explained how a friend of hers, who was in the intervention group, had shared some of the messages she had received. This control participant was particularly enthusiastic about the messages and reported that she would not have been able to tell her partner about her test result had it not been for the support and tips provided through the texts. Sharing was not always intentional. One young woman said that her mother had seen the texts, and although her mother was initially angry on learning that her daughter had had a positive chlamydia test, after talking through the texts with her daughter she felt that the texts were a good idea.

An important aspect of sharing messages for some was to help to initiate a conversation, usually with a partner. For example, messages were used by some women to support or back-up negotiations on condom use.

> *I've shown him a few (messages) about condoms and that but he wasn't listening to me and I was like oh my God … then show him the messages, yeah.…he's like well, I'm not fussed about it. I'm so like worried about it and like I know a lot about it now … I told him about that oh if I caught this again … I'd rather have a condom than catch an infection again. At first he was just like "Oh, like I really don't like it" but after he's seen the get pregnant or something in the future (reference to texts relating to infection and risk to infertility) which made him think as well. So I think like when you look into it deeper it helps a lot.* [ID03006, F, 18, Intervention, chlamydia positive]

Not all partners were as responsive:

> *He didn't really pay any attention, he was just like, "Oh you've got one of them texts again," you know* [ID03024, F, 16, Intervention, chlamydia negative]

Impact on Knowledge

Participants' reports regarding the impact of the intervention on knowledge varied. At one end of the spectrum there were those who reported that they knew little about STIs or how to use a condom.

> *Well, there was this one, yeah, that said how to put a condom on, the best...(Laughs) The quick and fresh way to put a condom on... (Laughs) Because I didn't know that much about condoms so I followed the link (to obtain further information) and I'm like, oh and it feels good when I learned how to put it on, you don't have to use something that got oil, yeah, you don't have to use it because the condom might burst and something like that ... oh I didn't know that's how you get it (chlamydia), I didn't know, I was like, oh I need to be more careful then, I need to use a condom mostly when I meet someone new.* [ID01002, F, 22, Intervention, chlamydia positive]

The topics reported to be particularly helpful included how to put a condom on, how to prevent condom breakages (eg, not using oil-based lubricants), STI testing, how to talk to a partner and messages relating to building confidence, and reducing the stigma and worry about the health concerns related to the chlamydia test result.

While some of the participants reported that they already knew most of the information, they said the messages reminded them of what they had learned in the past, reinforced this information or helped them reflect on what they knew.

> *Most of the stuff I knew but it kind of gave me a thought, because you don't really think about it sometimes at the time that you're getting into anything, you just kind of do what you're doing, but because of the texts it kind of keeps it in your mind so you know what you're doing really before you get into anything.* [ID01043, M, 18, Intervention, chlamydia negative]

> *I think everyone should have this texting thing come out to them every day because sometimes you do forget little things that obviously you should be doing.* [ID03013, F, 21, Intervention, chlamydia positive]

Some participants did not find the texts helpful, describing the messages as "common sense". They tended to be older and/or negative for chlamydia at enrolment. However, they generally felt that the advice was good, but would be better targeted at those 16-18 years of age. Participants had the option to text "Stop" if they wanted to discontinue receiving the messages. One had done this and he explained that he would have preferred more "scary facts...to make kids think" (ID01042, M, 21, Intervention, chlamydia negative). One of the female participants who had sexual relationships solely with women felt that the messages on condom use and contraception, for example, were not relevant for her.

Influence on Behavior

Partner Notification and Treatment

Nearly all those diagnosed with an STI in the intervention and control groups reported feeling able to notify their sexual partners of their test result. The exception was one young woman who had no contact details for a casual partner. Some of those in the intervention group said notification was done before receiving the texts, but others said that the texts about talking to your partner had helped them to have this discussion.

Participants reported lacking confidence in telling a partner about an infection and it was particularly helpful to receive messages about how others had done so. The mode of delivery was compared favorably with the approach adopted in health care settings which was described as more didactic.

> *When they told me first, yeah, at the hospital you have to tell him, I'm like no, I'm not going to tell him and they're like, do you want us to call him? I'm like, no, I'm not going to give you his number and they're like, well you have to, (laughs), you know, you have to tell him. I'm like, no, I don't know how to, anyway, you have to, just find a way to tell him. So I wasn't that confident ... but when I start this group (participation in the study) and they start telling me about chlamydia, that it's not that dangerous, you can cure it, ... you have to get tested and all that so it actually helped me a lot.* [D01002, F, 22, Intervention, chlamydia positive]

All participants diagnosed with chlamydia said that they and their main partner had been treated and that they had not had sexual intercourse in the week following treatment.

Reassurance and Reduction of Stigma

The information received in text messages that chlamydia is common, that you may not know you have it, and that it is easily curable was said to have reduced concerns and stigma, which in turn increased confidence in telling a partner. Some described being distressed after receiving a positive chlamydia result and the text messages were able to give them some reassurance. They reported being able to tell partners about an infection without blaming them or being blamed.

> *It basically said like not to blame him kind of thing 'cos, so ... it made it easier for me to handle the fact that I had it as well as the fact that obviously I needed to tell him so it was more comfortable like 'cos I wasn't like angry or whatever.* [ID03003, F, 19, Intervention, chlamydia positive]

The texts were also seen as helping to manage their own or their partner's anger and re-enforce that they had "done the right thing" in telling their partner.

> *Well I got the text and it was like 'Best way to tell your partner, sit down and explain it, and just say "Look, we both need to get treated". So I did, I told him, he kicked off first of all, he weren't very happy, and he was like 'You've cheated on me'. I was like 'No I haven't, you blatantly know'. Then we stopped speaking for a couple of days, and then he said 'Yeah, it's cool, I've been treated' … but yeah, that was basically it.* [ID03007, F, 16, Control who had read texts of friend in the Intervention group, chlamydia positive]

> *I probably would of (notified her partner) because even though I don't like him and even though I think that this whole problem is caused from him … I wouldn't want it to be passed onto anyone else, … but then this sort of study has shown me that that's the right thing to do and really you should just tell someone.* [ID03013, F, 21, Intervention, chlamydia positive]

Condom Use and STI testing

Some young people in the intervention group said that they were now using condoms following their chlamydia test result and receiving the texts.

> *I've been with him for eight months, it's like before I met him I didn't use like condoms and stuff and then obviously when I found out I had chlamydia I've used one every single time, like 'cos obviously I know how to put them on now... I don't have a problem using them now, so it's helped me in that sense as well.* [ID03003, F, 19, Intervention, chlamydia positive]

When asked whether their behavior change was due to their positive chlamydia result or the texts, some interviewees felt that the texts had helped improve their use of condoms. For example, in response to the interviewer question "... do you think that's more to do with the texts or was that because you got diagnosed with chlamydia?", one said:

> *No, the texts, the slogans. One of the texts were … 'use a condom' or something like that, and I thought 'Yes, I'm doing that!'* [ID03007, F, 16, Control group – read texts of friend in the Intervention group, chlamydia positive]

One woman was of the view that the text messages would not be sufficient for her to change behavior as it would be not be possible to introduce condoms if a partner refused.

> *My partner don't like them so I've never used them before, yeah. Whenever I tell him to use them, he's like no, you're my wife, I'm not going to use them. You know how... (Laughs) … African men are like, no. (Laughs) … they're like, you're my wife so I'm not going to use it. We're not married but that's what he always says, oh you're going to be my wife so there's no point of you using them. Yeah, so and I like him, I love him, so I'm like, okay, I'm not going to use it then.* [ID01002, F, 22, Intervention, chlamydia positive]

Some in established relationships said they would not be using condoms with their current partner, but their intention would be to use them with any future partners and to go for chlamydia screening.

> *But beforehand I didn't really think about it, I just used to go 'yeah, that'll be fine, it'll never happen to me'... cos I don't really use, well I only ever had one*

> *one-night stand anyway but, I've got a missus now anyway, but we don't use a condom now, but if I did sleep with someone else now, if I split up and then see someone else I would definitely use a condom now.* [ID03012, M, 24, Intervention, chlamydia positive]

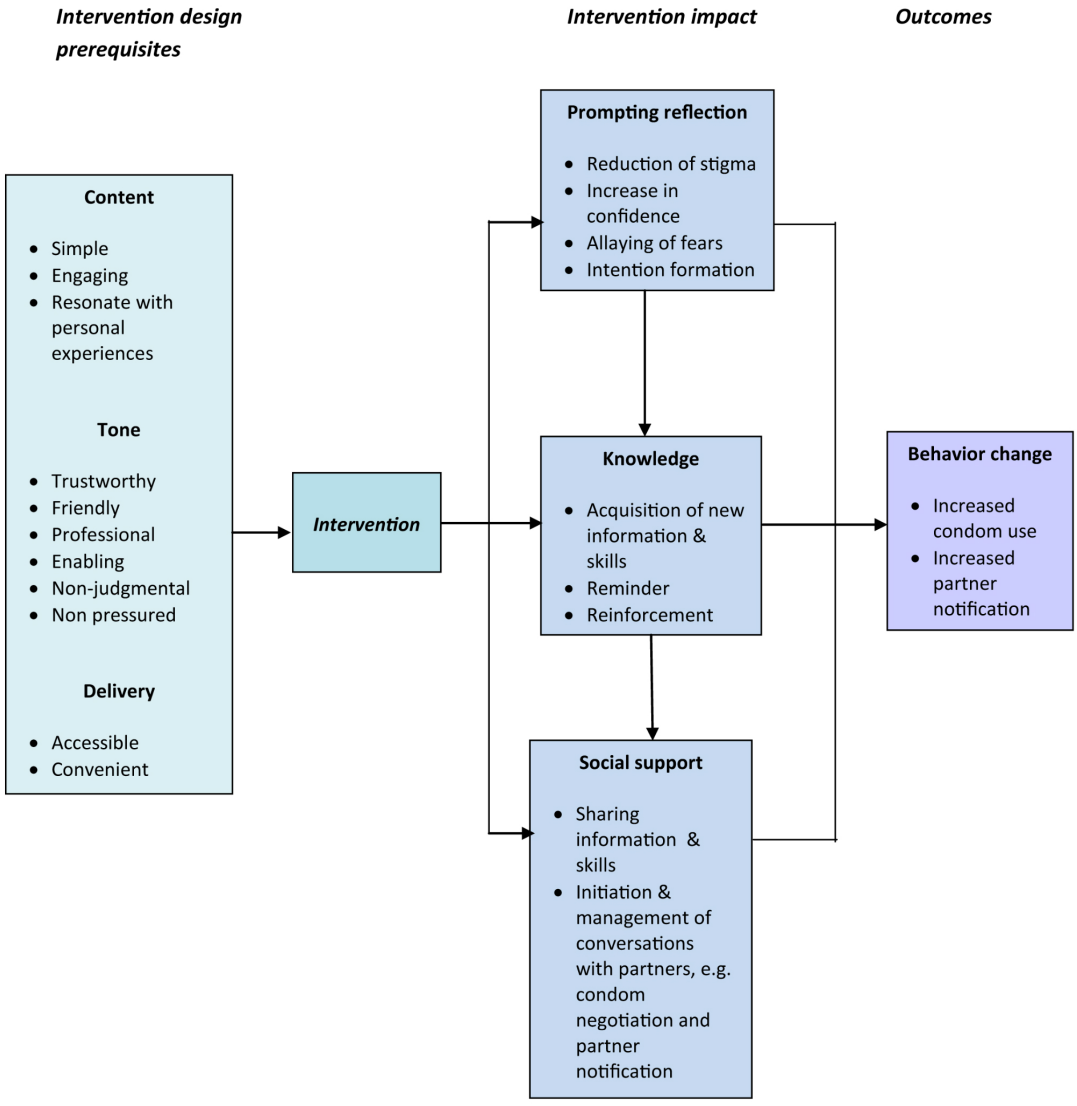
Some expressed the intention to go for screening check-ups and to ask their partners to do so in the future. Participants reporting behavior change were more often younger, had received a positive STI test result and/or were those not living in an inner-city setting.

Mechanism of Action

Coding and analyzing the interviews led to the development of a theoretical framework for the mechanism of action, including how the intervention is hypothesized to work at increasing safer sex behaviors. The prerequisites for content and delivery and the mechanism of action are illustrated in Figure 1. The findings from the interviews suggest that the intervention could work by providing information and skills to young people via a channel that is convenient and acceptable to them. For example, the texts appeared to help by providing new knowledge on how to put a condom on or having a reminder text facilitating condom use, and breaking down assumptions about how chlamydia infection is transmitted. The messages could also work by allowing recipients to reflect on their behavior and/or help them talk to their partner about the importance of protecting themselves against STIs, such as giving them the words which could be used when having these discussions or sharing the actual texts. The fact that this was done in a way which reduced stigma and was not pressured or judgmental assisted the communication with others.

There was less suggestion from the interviews that attitudes had shifted. The one exception was in relation to stigma. Stigma associated with STIs can result in young people not accessing appropriate care and services [23], therefore its inclusion in health promotion interventions addressing sexual health is key.

Figure 1. Prerequisites and mechanism of action.



Discussion

Principal Findings

The majority of young people we interviewed were positive about the mobile phone texting intervention to promote safer sex, particularly as it was convenient and took little of their time. The frequency, timing, and tone of the texts were appropriate for most. Receiving information and support in simple bite size messages was reported to help participants retain information. The text message medium also enabled participants to save and reflect on messages in their own time and share messages. Sharing texts provided participants with the opportunity to educate friends and siblings and acted as a prompt for discussions about sexual health and safer sex behaviors with partners. Text messages reportedly improved knowledge and confidence, and had a positive effect on safer sex behaviors, including condom use, STI testing, and notification of partners about a positive STI test result and/or hastening notification of partners.

The nature of the short content and method of delivery made the messages more acceptable than more traditional methods of health promotion such as printed leaflets. The intervention was developed using theory, evidence-based effective behavior techniques, and expert and user views. The content was designed to address attitudes, information, and behavior skills, rather than induce fear which has found to be ineffective [18,24].

Discussion in Relation to the Existing Literature

Our findings highlighting the importance of trust, reduction of stigma, and convenience are consistent with research on what young people want from sexual health services [25]. In keeping with other research, participants viewed the mobile phone as an essential everyday item owned by most people, with easy-to-use technology [26,27]. The particular *push*, the fact that messages are sent to participants rather than retrieved by them [27], makes this a convenient, low-commitment way to receive and share information and gain support. The *always-on-you* nature of the mobile phone [28,29], enabled the mobile phone and the text messages to act as reminders and maintain the salience of sexual health behaviors. This is consistent with previous work which reported that text messages in smoking cessation acted as reminders and maintained the importance of quitting [30]. In sexual health, previous research has reported that text messages provided and reminded people of information [31]. The technology allowed participants to easily retain messages [32]. This enabled recipients to absorb information at their own pace and to refer back to messages and reflect on them in relation to their own experiences and behavior. Rereading messages has been reported in previous research where a text message-based intervention was used to support smoking cessation [30]. In this case rereading messages was used as a tool to sustain motivation for quitting rather than for reflecting on past and current behavior. Retaining messages also facilitated discussions with friends and family and partners. Retained messages were shown to partners to support participants in negotiating condom and in telling partners about being diagnosed with an STI. This is in keeping with previous research which has reported that women receiving text messages regarding contraception used this facility to retain messages to share messages and initiate conversations with partners about contraception [33]. The perception of the mobile phone as a highly personal object [32,34], combined with messages written in a non-judgmental tone may have underpinned experiences of the intervention providing support and increasing confidence. As others have shown, concern about *reputation* and perceived social expectations can inhibit communication [35], but by increasing confidence and allaying fears, our findings suggest that a text messaging intervention has the potential to provide young people with skills to overcome some of the barriers to partner notification.

The favorable reception of our text messaging intervention among the young people we interviewed resonates with findings from qualitative studies in Australia and in the United States, which have found that sexual health promotion interventions delivered via text messaging are an acceptable and convenient way to deliver potentially sensitive information and support to young people [36,37]. In accordance with our findings they found that young people favored simple messages, they reflected on the content and that they shared messages with friends. The Australian study reported no change in condom use [36].

The suggestion in our study that the text messages had a positive effect on the promotion of safer sex behaviors, particularly with reference to providing encouragement, support, and skills relating to partner notification have strong implications for infection control. Mathematic modeling suggests that the expected probability of rate of chlamydial re-infection without partner notification is 19.4%; however, if a partner receives treatment within three days after receiving treatment, this is reduced to 4.2% [38]. It is estimated that only around 40% to 60% of sexual contacts are notified by patient referral [39,40], so new strategies are needed to help improve the partner notification process. If the difficulties of notifying a partner can be lessened by giving young people the necessary skills to expedite the process, as was described in our study, and reduce time to treatment, the number of contacts informed through patient referral is likely to increase. If our trial shows the intervention is effectives it will be low cost and could be integrated with electronic systems so it is automatically sent to patients when they receive test results.

Strengths and Limitations

The formative work done with the target group in the development of messages was key to the intervention's acceptability. Interviews were conducted shortly after participants had received the messages in order to minimize problems with recall. Our sampling strategy ensured that there was representation of different age groups, genders, and settings, so that a broad range of views could be included.

There are challenges in conducting research by telephone, for example telephone interviewing may have resulted in more superficial and briefer responses to questions than would have been the case if the interviews had been conducted face to face [41]. However, given the nature of the intervention this was an appropriate method which allowed us to interview geographically dispersed individuals. We are reliant on young people's self-reports which may differ from actual behavior,

and we were unable to explore the extent to which any behavior change might be sustained. Young people may have provided responses that they felt would be desirable for the interviewer to hear, and they may have also felt that they needed to be positive about the intervention itself. We tried to minimize this effect by getting a member of the team (RF) who was not directly involved with recruiting participants or the day-to-day running of the project to conduct the interviews.

Future Directions

The findings from these qualitative interviews will be used to adapt the intervention prior to an evaluation in a full scale RCT. Suggestions for improvements included refining messages so that they are relevant to lesbian, gay, bisexual, and transgender young people. Techniques could be provided to young people in established relationships on how they can negotiate behavior change without impacting on trust and intimacy. Contamination between the intervention and control groups was identified during the interviews. This could potentially lead to an under-estimate of any treatment effect. Because some participants reported sharing their text messages, we will measure this in the main trial in order to take into account any effect of contamination. However, in real-world implementation the interviews illustrate how the sharing of text messages is a good way of disseminating information and encouraging discussion. The collection of biological markers, using vaginal self-swabs for women and urine for men to test for STIs, will allow us to validate reported outcomes in a main trial. The qualitative interviews suggested the intervention may have a greater impact on the younger participants and the effect of the intervention on participants by age will also be investigated.

Conclusion

Our research found that a mobile phone-based texting intervention was acceptable to young people and the interviews suggested it helped promote safer sex behaviors, including increased condom use and partner notification. A full scale RCT is required to establish the effects of the intervention on the acquisition of STIs.

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Ethical approval for the pilot trial (of which this qualitative study is a component) was obtained from the NRES Committee South East Coast-Surrey.

Authors' Contributions

RF conducted all interviews with one exception (conducted by OM). Coding framework agreed by RF, OM, and CF. RF led on the analysis and writing up. CF is the principal investigator for the study and OM is the study coordinator. All authors have contributed to the study design and commented on drafts of this paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Number of messages received by participants.

[PDF File (Adobe PDF File), 309KB - mhealth_v4i2e26_app1.pdf]

Multimedia Appendix 2

Topic guide.

[PDF File (Adobe PDF File), 276KB - mhealth_v4i2e26_app2.pdf]

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Abbreviations

RCT: randomized controlled trial
STI: sexually transmitted infection

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Original Paper

Evaluating the Maintenance of Lifestyle Changes in a Randomized Controlled Trial of the 'Get Healthy, Stay Healthy' Program

Brianna S Fjeldsoe[1], PhD; Ana D Goode[1], PhD; Philayrath Phongsavan[2], PhD; Adrian Bauman[2], PhD; Genevieve Maher[1], MPH, MD; Elisabeth Winkler[1], PhD; Elizabeth G Eakin[1], PhD

[1]School of Public Health, Cancer Prevention Research Centre, The University of Queensland, Herston, Brisbane, Australia

[2]School of Public Health, The University of Sydney, Sydney, Australia

Corresponding Author:
Brianna S Fjeldsoe, PhD
School of Public Health
Cancer Prevention Research Centre
The University of Queensland
Public Health Building
Herston Rd
Herston, Brisbane, 4502
Australia
Phone: 61 73365 5435
Fax: 61 73365 5540
Email: b.fjeldsoe@sph.uq.edu.au

Abstract

Background: Extending contact with participants after initial, intensive intervention may support maintenance of weight loss and related behaviors.

Objective: This community-wide trial evaluated a text message (short message service, SMS)-delivered, extended contact intervention ('Get Healthy, Stay Healthy' (GHSH)), which followed on from a population-level, behavioral telephone coaching program.

Methods: This study employed a parallel, randomized controlled trial: GHSH compared with no continued contact (standard practice). Participants (n=228) were recruited after completing a 6-month lifestyle telephone coaching program: mean age = 53.4 (standard deviation (SD)=12.3) years; 66.7% (152/228) female; mean body mass index (BMI) upon entering GHSH=29.5 kg/m2 (SD = 6.0). Participants received tailored text messages over a 6-month period. The message frequency, timing, and content of the messages was based on participant preference, ascertained during two tailoring telephone calls. Primary outcomes of body weight, waist circumference, physical activity (walking, moderate, and vigorous sessions/week), and dietary behaviors (fruit and vegetable serves/day, cups of sweetened drinks per day, takeaway meals per week; fat, fiber and total indices from the Fat and Fiber Behavior Questionnaire) were assessed via self-report before (baseline) and after (6-months) extended contact (with moderate-vigorous physical activity (MVPA) also assessed via accelerometry).

Results: Significant intervention effects, all favoring the intervention group, were observed at 6-months for change in weight (-1.35 kg, 95% confidence interval (CI): -2.24, -0.46, *P*=.003), weekly moderate physical activity sessions (0.56 sessions/week, 95% CI: 0.15, 0.96, *P*=.008) and accelerometer-assessed MVPA (24.16 minutes/week, 95% CI: 5.07, 43.25, *P*=.007). Waist circumference, other physical activity outcomes and dietary outcomes, did not differ significantly between groups.

Conclusions: The GHSH extended care intervention led to significantly better anthropometric and physical activity outcomes than standard practice (no contact). This evidence is useful for scaling up the delivery of GHSH as standard practice following the population-level telephone coaching program.

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KEYWORDS

maintenance; mHealth; physical activity; exercise; diet; nutrition; text message; behavior change

Introduction

Behavioral interventions can effectively promote weight loss [1,2]. Maintaining improvements in weight and related behaviors following the end of interventions is challenging [3-9]. Evidence from maintenance-focused interventions for physical activity, diet, and weight suggests the need for extended contact after initial intervention [10-12]. This contact can reinforce skills learned during the initial intervention, support ongoing problem solving, and provide continued accountability and motivation. Two meta-analyses of extended contact trials for weight loss concluded that they are viable and efficacious [12,13]. These meta-analyses (and other narrative reviews [14,15]) show that most extended contact interventions were delivered via face-to-face sessions, even though face-to-face session attendance decreases over time and as individuals regain weight [7,16]. There is some support for telephone-delivered extended contact interventions [16-20] and mixed evidence for Web-based extended contact interventions [12,21], with poor results being attributed to the lack of ongoing engagement with the website.

Text messages (short message service, SMS) may be a suitable, low-cost delivery modality for extended contact. It can: deliver tailored, repeated contacts; be actively "pushed" to participants; prompt behaviors in real time; and maintain two-way communication with an interventionist using minimal resources. Two recent pilot studies reported maintained weight loss in participants receiving a text message-delivered extended contact intervention [22,23]. This area of research has substantial promise for population health.

The Get Healthy Information and Coaching Service (GHS) is a population-wide telephone-delivered coaching program targeting weight loss, physical activity, and healthy eating in Australian adults [24]. Evaluations of the GHS have shown meaningful community-level weight loss and behavioral improvements at the end of the 6-month program [25] and, in a small subsample of participants, evidence of maintenance for weight loss and some behavioral outcomes, 6 months after completion [26].

The 'Get Healthy, Stay Healthy' (GHSH) randomized controlled trial compared a text message–delivered extended-contact intervention with standard practice (no contact) in GHS program completers. Primary outcomes for examining effectiveness of GHSH were: body anthropometry (weight, waist circumference), physical activity (self-reported walking, moderate and vigorous sessions/week, accelerometer-assessed moderate-vigorous physical activity minutes/week), and dietary behaviors (fruit and vegetable serves/day, cups of sweetened drinks/day, takeaway meals/week; fat, fiber, and total indices from the Fat and Fiber Behavior Questionnaire (FFBQ)). Secondary outcomes related to feasibility, acceptability, and costs of delivering GHSH.

Methods

Study Design

Data were collected at baseline (at GHS completion), 6 (end of GHSH extended contact), and 12 months (6 months following GHSH completion). Recruitment began in August 2012 and 6-month follow-up data collection were collected until March 2014. This paper reports on the baseline and 6-month data. Ethical clearance was received from the Human Research Ethics Committee at The University of Sydney (Protocol No.: 03-2011/13523). A detailed description of the trial methods is published elsewhere [27].

Participant Recruitment

Eligibility criteria were: lives in New South Wales, Australia; no intention of re-enrolling in GHS coaching; not involved in other GHS evaluations; and owns a mobile telephone. All eligible clients completing the GHS within the recruitment timeframe were invited to participate during their final coaching call. Interested participants were mailed an information sheet and consent form and then contacted via telephone to establish their eligibility and willingness to participate. Verbal consent to participation was audio recorded and participants returned a signed consent form via reply paid post.

Randomization

Participants were randomized 1:1 to GHSH intervention and control conditions, in two strata (GHS weight loss ≥ or < median of 3-kg loss), via a randomization website. This was done by a research assistant with no involvement in participant recruitment.

The Get Healthy, Stay Healthy Intervention

The Get Healthy, Stay Healthy (GHSH) intervention was delivered via individually tailored text messages, with tailoring data collected during two telephone calls. Participants chose to focus on a weight loss or weight maintenance goal, and on physical activity or diet or both (with targets consistent with national guidelines) [28,29].

Initial Tailoring Call

This telephone call was scripted, and conducted by a trained health coach (not a GHS coach). Participants set a goal for weight maintenance or further loss within 3 months, and then two goals for behavior change. For each behavioral goal, they were asked to identify: rewards for reaching their goal; expected benefits; preparatory behaviors for goal attainment; barriers and solutions; and a person who could support them to reach their goals. Participants selected their desired number of text messages (from 3-13 per fortnight), timing of texts (eg, 6 AM), and type of texts (from the four types described below). This information was recorded during the call and was used to tailor GHSH texts.

Get Healthy, Stay Healthy Text Messages

Four types of texts targeted different behavior change strategies, each with different permitted frequencies (an example of each text type has been previously published [27]):

1. Prompts to self-monitor weight (once per fortnight).
2. Goal check text messages (from once per fortnight to once per week for each behavioral goal) that asked participants to reply "yes" or "no" to indicate their attainment of behavioral goals in the past week. Participants received a

tailored goal check reply text message based on their yes/no response.

3. Real-time behavioral prompts (from none to four per fortnight for each behavioral goal) that remind participants of their goals, preparatory behaviors, and anticipated barriers and solutions.
4. Two goal reset text messages (one in week 6 and one in week 18) that prompt participants to consider their weight and behavioral goals and reset them appropriately. Participants were encouraged to tell their GHSH coach their new goals via reply text and these changes were reflected in subsequent texts.

Wording of the text messages (each ≤160 characters) was tailored to each individual's name, gender, goals, identified barriers and strategies, preparatory behaviors to achieve their goals, expectations of behavioral change, and the first name of their identified support person. Texts were generated and sent by research staff, using a purpose-designed software package in which messages were preprogrammed in advance and scheduled to be sent at specific times. Replies to the goal check texts were stored and automatically triggered tailored responses whenever the participant replied with "yes," "no," or accepted variations of these. Whenever participants' goal check reply contained additional words or an unrecognized variant of "yes" or "no" the program emailed research staff who manually decided which tailored reply to send. Unprompted reply text messages from participants did not receive a reply. At any stage participants, could change their text message preferences via text message or telephone call.

Twelve-Week Tailoring Call

At 12 weeks, participants received a second telephone call from their coach to update their tailoring information. This call was made between weeks 12 and 14, and if contact was not made during this period, the existing tailoring information was used for the final 12 weeks.

Control Group Treatment

To minimize trial attrition, control participants were posted brief written feedback of results following each assessment. The control group received no other contact.

Data Collection

The anthropometric and behavioral measurement tools used in this study were the same as those used in the GHS evaluation to enable comparison. More detailed data on MVPA and dietary behaviors were also collected at baseline and 6-months via: a computer-assisted telephone interview (CATI) conducted by a research assistant, a paper-based questionnaire, and a posted accelerometer. The research assistant was blinded to group allocation at baseline, but participants may have mentioned treatment during the 6-month CATI and so blinding was not guaranteed. Participants had previously provided demographic data and data on change in primary outcomes during the initial GHS.

Primary Outcomes

Anthropometric Outcomes

During the CATI, participants reported their body weight in kilograms (while wearing light clothes and no shoes). They were encouraged to weigh themselves during the CATI if scales were present; otherwise, they were asked to report their most recent weighing. Participants were posted a measuring tape and instruction sheet on measuring waist circumference at baseline. The interviewer instructed participants to take the waist circumference measurement during the call. Body mass index (BMI) was calculated based on self-reported height at GHS baseline and self-reported weight at each assessment point. These self-report methods have been validated against objectively measured weight and waist circumference in a subsample of GHS users (n=38) [25]. This validation study showed strong correlations (Spearman rho >0.90) with the objective measures for both outcomes. There were 84% and 87% agreements in BMI and waist circumference classifications, respectively [25].

Physical Activity

During the CATI, participants completed a validated, 3-item assessment tool (3Q-PA) which asked about the number of weekly sessions spent: walking for ≥30 minutes; doing other moderate-intensity physical activity for ≥30 minutes (termed "moderate"); and, doing vigorous-intensity physical activity for ≥20 minutes [30].

Participants were also posted a belt-mounted dual-axis accelerometer (Actigraph model GT1M) initialized to collect data in 10-second epochs, a wear-time log, and a reply-paid envelope to return their materials. Participants were asked to wear the monitor on the hip for 7 consecutive days during all waking hours, and to remove the monitor only for sleep (if desired) and during times the monitor could be damaged (eg, during water-based activities). The wear log included monitor-fitting instructions and asked about any monitor removals, sleep time, and whether the monitor was worn or removed during sleep. Accelerometer data were downloaded in Actilife (v 6.6.2). Both 10- and 60-second epoch files were processed in SAS version 9.3. Nonwear time was excluded (ie, ≥60 minutes of 0 counts per minute (cpm), allowing for up to 2 minutes of 1 to 49 cpm [31]) and only days with ≥10 hours of wear were deemed valid. Data were plotted (as heatmaps) and compared against wear logs. Any sleep not already excluded as nonwear was excluded, along with any days that had registered as valid but the monitor was in the post. All minutes with ≥1952 cpm (vertical axis [32]) were classed as MVPA, then summed for each day and averaged across valid days.

Dietary Behaviors

During the CATI, participants reported the following: number of daily servings of fruit and of vegetables [33]; average daily consumption of sweetened drinks (cordials, fruit juices, sports drinks, soft drinks not including diet soft drinks); and takeaway meals per week [34]. Participants also completed the FFBQ [35], which asks about consumption of high-fat and high-fiber foods over the previous month concerning cooking, eating and food choice behaviors, and two items regarding fruit and

vegetable intake. The average of the relevant items (1-5, with higher values indicating healthier habits) form the three FFBQ indices (20-item Total Index, 13-item Fat Index, and 7-item Fiber Index). These have good reliability, acceptable validity and good responsiveness to change [35].

Secondary Outcomes

Feasibility Indicators

The text message software collected data on delivery (ie, number and type of text messages sent) and intervention engagement (ie, number of responses to goal check texts and achievement of weekly behavioral goals). The duration of the tailoring interviews and participant alterations to text preferences were tracked by research staff.

Acceptability Indicators

At 6 months, intervention participants rated satisfaction and usefulness in five categories ("not at all" to "extremely" satisfied/useful), of the GHSH intervention overall and specifically regarding support for achieving behavioral and weight loss goals. Intervention participants were invited to complete a telephone interview with research staff (approximately 10 minutes) involving open-ended questions regarding intervention usage, satisfaction, and potential program improvements. These interviews were audio-recorded, transcribed verbatim, and coded independently by two authors. Discrepancies between coding were discussed until consensus was reached and recruitment stopped once thematic saturation was reached.

Costs of Intervention Delivery

Personnel time was tracked for delivering all intervention-related tasks. Coach time was costed at AU$37.56 per hour and research staff time was costed at AU$31.56 per hour. Average duration per participant (minutes) was multiplied by the relevant personnel cost. Direct costs of sending the texts (at AU$0.15 each) were tracked, totaled and then divided by the total number of intervention participants to provide a per participant cost.

Sample size

The sample size was chosen a priori to provide ≥90% power to detect the following expected differences between groups in primary outcomes: two sessions/week of self-reported MVPA; one serving of fruit per day and one serving of vegetables per day; 2-kg body weight; and 4-cm waist circumference as previously reported [27]. These were larger than the minimum differences of interest (MDI) in ascertaining that a group difference is not meaningful or change is less than a meaningful amount (maintained). MDIs were: 1-kg weight, 1-cm waist circumference, 30 minutes or 0.5 sessions/week physical activity, 0.5 servings/day fruit and vegetables, 0.5 takeaway meals/week, 0.25 cups/day sweetened drinks and 0.2 units on the FFBQ Indices. Power was adequate (≥80%) to detect these MDIs only for the dietary outcomes other than vegetables. The study was not powered a priori for questions concerning within-groups changes.

Statistical Analysis

Analyses were performed in SPSS version 22 and STATA version 13. Significance was set at $P<.05$, two-tailed. Analyses were based on intention-to-treat principles, analyzing all participants (not subgroups) as randomized, but a small amount of missing data was excluded (completers' analysis). Intervention effects (between-group differences, intervention minus control) were assessed using regression models that adjusted for baseline values of the outcome to control regression to the mean, the randomization strata (GHS weight loss ≥ or < median of 3-kg loss) and potential confounders that were associated with the outcome at $P<.2$ (Multimedia Appendix 1). The broader GHS evaluation reported mean changes; for comparability, we report paired *t*-tests for changes within groups during the GHSH trial (baseline to 6 months) and for prior changes during the GHS evaluation. Intervention effects and within-groups changes for MVPA (log-transformed) were assessed using generalized estimating equations (GEE) to account for repeated measures (daily), and adjusting for predictors of missing data ($P<.2$) (Multimedia Appendix 1).

Sensitivity Analyses

Intervention effects were re-examined using multiple imputation by chained equations in STATA (m=20 imputations), adjusting for the same covariates as the completers models as well as predictors of missing data ($P<.2$). Alternative models assessed whether conclusions were affected by model choice, as the main models sometimes failed to meet requisite assumptions. For count outcomes, intervention effects were retested using negative binomial models or zero-inflated negative binomial models when these fit the data better (Vuong test) [36]. The zero-inflated models were best suited to modelling the behaviors (physical activity, soft drink, and takeaway meal consumption) in which many participants did not engage.

Interpretation of Findings

It is complex to interpret results from extended contact interventions where "no change" in outcomes can be interpreted as a positive finding. Within-group changes ("worsened" or "improved") and between-group differences (intervention "better" or "worse" than control) were only claimed when these were statistically significant. As nonsignificant findings can indicate either no change/difference or an insufficient sample size to yield a conclusive finding, we only described outcomes as "maintained" or as groups being "similar" if in addition to the finding being nonsignificant, the likely true effect size for the change/difference as indicated by the 95% confidence interval (CI) was also very small (<MDI).

Results

Participants

There were 1071 clients invited to participate in this study, of whom 300 expressed verbal interest in participating in the trial, and 228 participants consented and were randomized (228/300, 76%; Figure 1). Table 1 shows the demographic characteristics of GHSH participants (intervention, n=114; control, n=114). Upon entering the GHSH trial, participants (152/228, 67% female) had a mean age of 53.4 (standard deviation (SD) = 12.3)

years and BMI of 29.5 kg/m^2(SD = 6.0), 34% (78/228) were overweight and 38% (87/228) were obese, 40% (91/228) did not meet physical activity guidelines [28] (ie, <150 minutes MVPA per week), and 80% (182/228) did not consume the recommended serves of fruit (ie, two) and/or vegetables (ie, five) per day [29].The GHSH sample was not representative of all participants completing the final GHS coaching call. Odds of being in the GHSH trial were significantly higher than their respective counterparts for those: aged <60 years; not working; without a post school qualification; self-reported diagnosis of hypertension; self-reported diagnosis of high cholesterol; doing no vigorous activity; and, who consume <1 takeaway meal per week (Multimedia Appendix 2).

The overall retention rate from baseline to 6 months was 95% (216/228) (103/114, 90% in intervention and 113/114, 99% in controls, *P*=.005). Most intervention participants (98/114, 86%) and controls (107/114, 94%) had full data on all outcomes at 6-month follow-up and on the baseline and prestudy covariates examined (*P*=.077). Missing data was associated with: higher baseline BMI (mean ± SD for missing vs complete;

Figure 1. Participation in the Get Healthy, Stay Healthy (GHSH) trial.

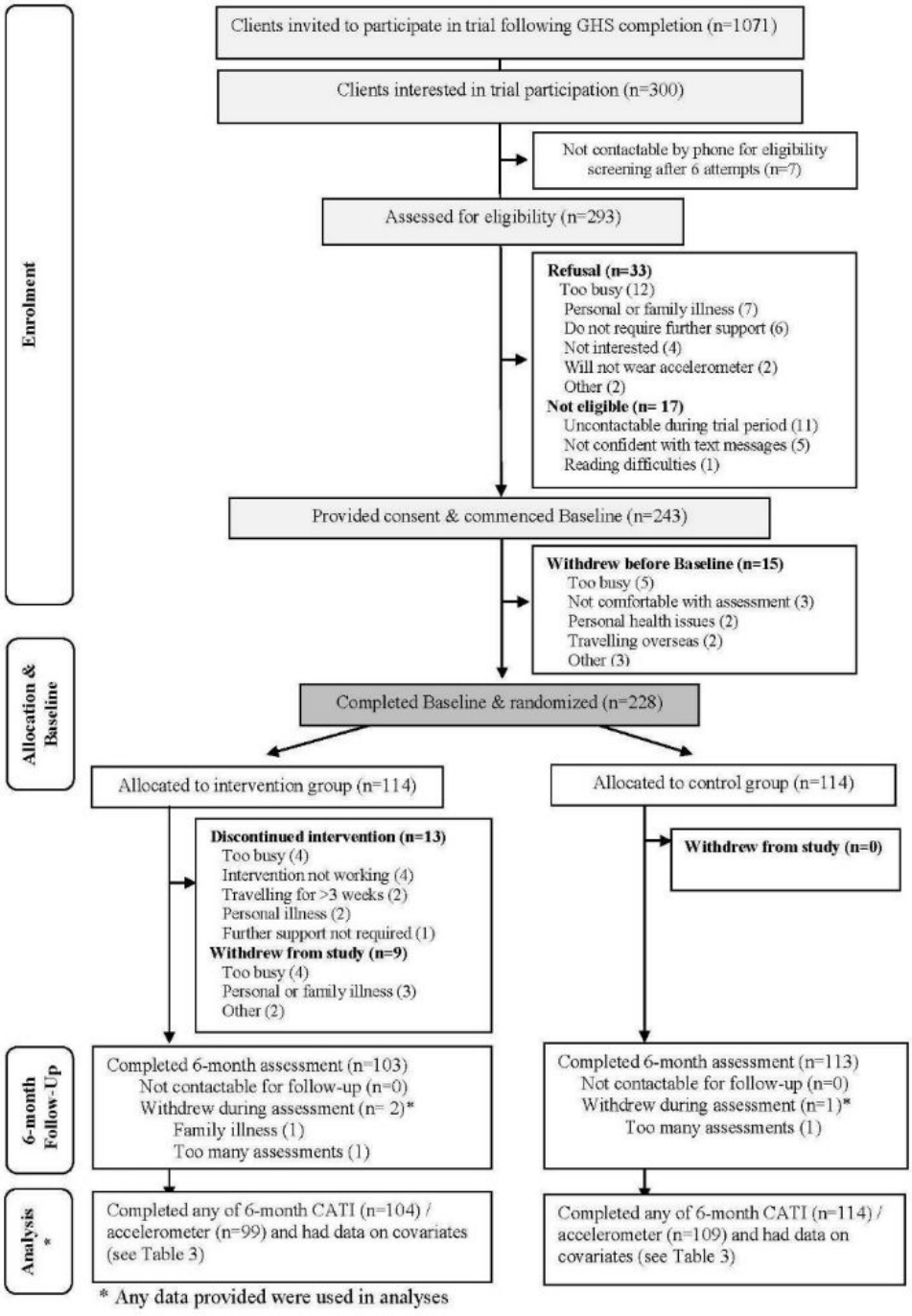

Table 1. Characteristics of 'Get Healthy, Stay Healthy' (GHSH) trial participants.

	Mean (SD) or n (%)	
	GHSH (n=114)[a]	Control (n=114)[a]
Health and demographics at baseline		
Age (years)	55.5 (12.3)	51.2 (11.9)
BMI (kg/m^2)	29.3 (5.8)	29.6 (6.3)
Weight (kg)	82.8 (19.4)	83.6 (18.9)
Waist circumference (cm)	98.9 (15.4)	99.6 (14.9)
Gender (% female)	74 (64.9%)	78 (68.4%)
In paid employment (% yes)	69 (61.1%)	68 (59.6%)
Education (% post-school qualification)	73 (64.0%)	77 (67.5%)
Indigenous Australian (%)	1 (0.9%)	5 (4.4%)
SEIFA[b](% living in most advantaged 3 quintiles)[c]	86 (75.4%)	78 (68.4%)
Region (% living in major cities)	71 (62.3%)	82 (71.9%)
Physical activity at baseline		
Accelerometer PA[d](minutes/week)	196.9 (144.4)	196.2 (143.6)
Vigorous PA (sessions/week)	1.56 (1.86)	2.33 (2.53)
Moderate PA (sessions/week)	1.11 (1.78)	1.60 (1.97)
Walking PA (sessions/week)	3.99 (3.04)	3.30 (2.44)
Dietary behaviors at baseline		
Vegetables (servings/day)	3.1 (1.4)	3.4 (1.8)
Fruit (servings/day)	2.0 (0.9)	2.0 (1.0)
Sweetened drinks (cups/day)	0.2 (0.5)	0.4 (0.9)
Takeaway (meals/week)	0.5 (0.8)	0.5 (0.9)
FFBQ Total Index (Score (1-5)	3.3 (0.4)	3.3 (0.4)
FFBQ Fat Index (Score (1-5)	3.5 (0.5)	3.5 (0.5)
FFBQ Fiber Index (Score (1-5)	2.9 (0.5)	2.9 (0.5)
Prior changes during GHS		
Weight (kg)	−3.7 (4.0)[e]	−3.8 (4.3)[e]
Waist circumference (cm)	−5.5 (5.0)[e]	−6.3 (5.7)[e]
Vigorous PA (sessions/week)	0.5 (1.4)[e]	0.6 (1.7)[e]
Moderate PA (sessions/week)	0.5 (2.1)[e]	0.9 (2.2)[e]
Walking PA (sessions/week)	1.7 (2.7)[e]	1.1 (2.6)[e]
Vegetables (servings/day)	1.2 (1.5)[e]	1.2 (1.4)[e]
Fruit (servings/day)	0.6 (1.2)[e]	0.7 (1.1)[e]
Sweetened drinks (cups/day)	−0.2 (0.6)[e]	−0.3 (1.2)[e]
Takeaway (meals/week)	−0.5 (1.6)[e]	−0.5 (1.5)[e]

[a]Figures exclude missing data: one GHSH intervention participant (employment, English spoken at home, referral source, accelerometer PA) and one control participant (waist circumference, Indigenous status).

[b]Socioeconomic Indexes for Areas.

[c]Specifically the Index of Relative Socio-Economic Advantage and Disadvantage.

[d]Physical activity.

[e]Statistically significant change during GHS (P<.05) based on t-test.

32.7 ± 7.3 vs 29.1 ± 5.8 kg/m^2, *P*=.006); higher baseline weight (90.8 ± 19.5 vs 82.3 ± 18.9 kg, *P*=.044); higher rates of Type 2 Diabetes at baseline (8/23, 34.8% vs 22/205, 10.7%, *P*=.004); higher rates of smoking at baseline (5/23, 21.7% vs 7/205, 3.4%, *P*=.003); and lower vegetable intake at baseline (2.5 ± 1.1 vs 3.4 ± 1.6 servings per day, *P*=.012) (Multimedia Appendix 3). Participant's reasons for discontinuing the intervention are shown in Figure 1, with the most common reasons being that they were too busy (4/13) or that the intervention was not working for them (4/13).

Anthropometric and Behavior Change Results

Anthropometric Outcomes

Intervention participants showed significant reductions in both body weight (−0.89 kg, 95% CI: −1.53, −0.25) and waist circumference (−1.34 cm, 95% CI: −2.31, −0.36; Table 2). Intervention group improvements were significantly greater than controls for weight loss (−1.35 kg, 95% CI: −2.24, −0.46, *P*=.003), but not for waist circumference (*P*=.115; Table 3).

Physical Activity

The intervention group maintained their accelerometer-assessed MVPA and self-reported vigorous activity, and changed significantly only in self-reported walking (−0.55, 95% CI: −0.99, −0.11 sessions/week; Table 2). The control group changed significantly in moderate activity and MVPA, which both declined (−0.68, 95% CI: −1.11, -0.26 sessions/week, and −16.10, 95% CI −28.60, −3.61 min/week; Table 2). The intervention group did significantly better than the control group in moderate activity (0.56, 95% CI: 0.15, 0.96 sessions/week) and in accelerometer-assessed MVPA (24.16, 95% CI: 5.07, 43.25 min/week; Table 3). Intervention effects for walking and vigorous activity were not significant (Table 3).

Dietary Behaviors

In the intervention group, small, but statistically significant improvements in dietary outcomes were observed for the FFBQ Fiber and Total Indices, while remaining dietary outcomes, except takeaway meals per week, were all maintained (Table 2). By contrast, in the control group, there were no statistically significant improvements, only statistically significant declines in vegetable intake and fruit intake (Table 2). Other dietary outcomes were maintained. No significant or meaningful intervention effect for dietary outcomes was observed.

Sensitivity Analyses

Results from analyses using multiple imputation mostly supported the interpretations from the main analyses (Multimedia Appendix 4), except that due to slightly narrower CIs in the multiple imputation analysis, the intervention group maintained takeaway meals/week (rather than being 'inconclusive') and the intervention effect for vegetable serves/day was 'similar' (rather than 'inconclusive'). Conclusions using the alternative models mostly supported the main findings (Multimedia Appendix 5) and revealed significant differences in walking (*P*=.018). The intervention group showed a greater tendency to walk than controls (odds ratio = 2.17, 95% CI: 0.45, 10.43, *P*=.334), but also to report fewer walking sessions when they did walk than controls (relative rate = 0.77, 95% CI: 0.64, 0.92, *P*=.005).

Feasibility Results

The mean (±SD) call duration was 34 ±8 minutes for the initial tailoring call and 18 ±8 minutes for the 12-week tailoring call. The median number of text messages requested during the initial tailoring call and at the 12-week tailoring call were both five per fortnight (25th-75thpercentiles =3-7 texts). During the initial tailoring call, 40% (46/111) of participants requested fortnightly goal checks for both behavioral goals; 35% (40/111) weekly for both goals; and, 22%(25/111) weekly for one goal and fortnightly for the other goal. Approximately one-half the participants (58/111, 52%) did not request any real-time behavioral prompts and 35% (39/111) requested between 2-4 prompts per fortnight. Almost all (89/95, 94%) intervention participants still enrolled at 12-weeks completed the 12-week tailoring interview. During the 12-week tailoring call, almost all (82/89, 92%) participants changed their preference for text message content, and 40% (36/89) changed their preferred text message schedule. Outside of the 12-week tailoring call, only 3% (3/90) of participants changed either of these preferences via text. The weight goal reset text received replies from 30% (33/111) of participants at week 6 and 26% (25/95) at week 18. At week 6, 40% (44/111) of participants reset at least one behavioral goal; 29% (28/95) did so in week 18. Intervention completers (n=90) replied to 84% of goal check texts sent in week 1 (152/180) and 69% (125/180) of goal check texts sent in the last week.

Acceptability Results

Most (69/99, 70%) participants rated GHSH as "useful" or "extremely useful" in supporting their weight goal, and 75% (74/99) reported that they were "satisfied" or "extremely satisfied" with the intervention. Follow-up interviews with 62 intervention participants revealed that: experience with text messaging prior to GHSH impacted on participants' experience during the intervention; the GHSH program often exceeded participants' expectations; and participants generally perceived the GHS and GHSH intervention to be one program. Reasons for liking GHSH focused on: the reminders provided by the text messages to reinforce what participants wanted to do; maintaining accountability; and increased awareness of behaviors in real time. The few participants who did not like aspects of the GHSH nominated text messages being too repetitive or automated as key reasons.

Costs of Intervention Delivery Results

Health coach staff spent, on average, 35 minutes per participant conducting and preparing for the initial tailoring interview and 30 minutes for the 12-week tailoring interview. Research staff spent on average 31 minutes per participant entering tailoring data into the software following the initial tailoring call and 15 minutes per participant after the 12-week tailoring call. Research staff had to manually trigger responses to 813 goal check replies not recognized by the software (813/2071, 39%) of responses received), which took approximately 1 minute per response. During the intervention, 8518 text messages were sent to participants (at AU$0.15 each) totaling AU$1278 (averaging

AU$11.21 per participant). Overall, it cost approximately AU$80.00 per participant to deliver the GHSH extended contact intervention.

Table 2. Mean changes within the 'Get Healthy, Stay Healthy' (GHSH) intervention group (I; n=104) and the control group (C; n=114)

	MDI	Group	Mean Change (6 months – baseline)[a]		Within−group interpretation
			Mean (95% CI)	*P*	
Anthropometry					
Weight (kg)	1 kg	I	*− 0.89 (−1.53, −0.25)*[b]	*.007*	Improved
		C	0.30 (−0.35, 0.95)	.357	Maintained
Waist circumference[c](cm)	1 cm	I	*− 1.34 (−2.31, −0.36)*	*.008*	Improved
		C	−0.32 (−1.47, 0.82)	.578	Inconclusive
Physical activity (PA)					
Vigorous PA (sessions/week)	0.5 session	I	0.20 (−0.10, 0.50)	.183	Maintained
		C	−0.40 (−0.86, 0.05)	.084	Inconclusive
Moderate PA (sessions/week)	0.5 session	I	0.19 (−0.16, 0.54)	.277	Inconclusive
		C	*− 0.68 (−1.11, −0.26)*	*.002*	Worsened
Walking PA (sessions/week)	0.5 session	I	*− 0.55 (−0.99, −0.11)*	*.015*	Worsened
		C	0.31 (−0.40, 1.01)	.392	Inconclusive
Accelerometer PA[d](minutes/week)	30 minutes	I	7.41 (−5.61, 20.44)	.265	Maintained
		C	*− 16.10 (−28.60, −3.61)*	*.012*	Worsened
Dietary behaviors					
Vegetables (servings/day)	0.5 serves	I	−0.17 (−0.46, 0.12)	.237	Maintained
		C	*− 0.41 (−0.71, −0.12)*	*.006*	Worsened
Fruit (servings/day)	0.5 serves	I	−0.06 (−0.22, 0.10)	.482	Maintained
		C	*− 0.22 (−0.39,−0.05)*	*.011*	Worsened
Sweetened drinks (cups/ day)	0.25 cups	I	−0.00 (−0.08, 0.08)	.982	Maintained
		C	−0.04 (−0.19, 0.11)	.602	Maintained
Takeaway (meals/week)	0.25 meal	I	−0.13 (−0.28, 0.02)	.379	Inconclusive
		C	−0.06 (−0.19, 0.07)	.079	Maintained
FFBQ Total Index Score (1–5)	0.2 units	I	*0.07 (0.02, 0.12)*	*.011*	Improved
		C	0.01 (−0.05, 0.07)	.781	Maintained
FFBQ Fat Index Score (1–5)	0.2 units	I	0.06 (−0.01, 0.13)	.082	Maintained
		C	0.03 (−0.04, 0.11)	.368	Maintained
FFBQ Fiber IndexScore (1–5)	0.2 units	I	*0.08 (0.01, 0.16)*	*.028*	Improved
		C	−0.03 (−0.12, 0.06)	.493	Maintained

[a]Mean changes estimated by paired *t*-test within completers, or by marginal means from GEE models for daily accelerometer MVPA (which was back-transformed from the log scale and multiplied by 7 yield minutes/week).

[b]Italic values indicate statistical significance at P .05.

[c]n=103 GHSH group; n=112 control group (item missing data for waist circumference).

[d]n=99 GHSH group; n=108 control group; some participants did not wear the accelerometer.

Table 3. Mean differences in changes between the 'Get Healthy, Stay Healthy' (GHSH) intervention (I; n=104) and control groups (C; n=114).

	Mean difference (GHSH – control)[a]		Between-group interpretation
	Mean (95% CI)	*P*	
Anthropometry			
Weight (kg)	*− 1.35 (−2.25, −0.46)*[b]	*.003*	significantly better
Waist circumference[c](cm)	−1.18 (−2.65, 0.29)	.116	inconclusive
Physical activity (PA)			
Vigorous PA (sessions/week)[d]	0.15 (−0.34, 0.63)	.547	inconclusive
Moderate PA (sessions/week)[d]	*0.55 (0.14, 0.96)*	*.008*	significantly better
Walking PA (sessions/week)	−0.69 (−1.46, 0.08)	.077	inconclusive
Accelerometer PA (mins/week)[e]	*24.16 (5.07, 43.25)*	*.007*	significantly better
Dietary behaviors			
Vegetables (servings/day)	0.15 (−0.21, 0.50)	.408	inconclusive
Fruit (servings/day)[d]	0.16 (−0.05, 0.37)	.133	similar
Sweetened drinks (cups/day)	−0.05 (−0.19, 0.10)	.537	similar
Takeaways (meals/week)	0.01 (−0.15, 0.18)	.864	similar
FFBQ Total Index Score (1–5)	0.05 (−0.03,0.13)	.195	similar
FFBQ Fat Index Score (1–5)	0.02 (−0.07, 0.12)	.615	similar
FFBQ Fiber Index Score (1–5)	0.08 (−0.03, 0.19)	.147	similar

[a]Mean difference (β) with 95% CI, and *P*value from linear regression models, adjusted for baseline values of the outcome and confounders (listed in Multimedia Appendix 1).

[b]Italic values indicate statistical significance at P .05.

[c]n=102 GHSH group; n=112 control group (item missing data for waist circumference).

[d]n=103 GHSH group; n=114 control group (item missing data for vigorous PA, moderate PA and Fruit).

[e]Estimated using marginal means from GEE models of log-transformed daily MVPA (repeated term for "day"), adjusting for confounders, and correcting for regression to the mean using the method [37] of including the term for assessment (pre/post) and the assessment x group interaction, but not the conditional term for group. Estimates were back-transformed to the original scale, then multiplied by 7 to yield minutes per week. n=112 GHSH group; n=114 control group (all participants with data at either time point examined).

Discussion

Principal Findings

Overall, the GHSH intervention was feasible to deliver and acceptable to participants. It led to significantly better outcomes compared with the control group in weight loss and some forms of physical activity, but not in dietary behaviors. For most dietary outcomes, meaningful intervention effects were also unlikely, based on the CIs. The study findings were inconclusive due to insufficient sample size for vegetable intake, walking, vigorous activity and waist circumference.

The GHSH weight loss of 0.89 kg (95% CI: −1.53, −0.25) during extended care was better than or consistent with comparable extended contact interventions. Spark and colleagues [23], in a single-group group trial of breast cancer survivors (n=29), found when receiving text message extended contact, women on average regained 1.3 kg (95% CI: −0.5, 3.1 kg) over 6 months. Donaldson and colleagues [22], in a small (n=34), nonparallel controlled trial, found intervention participants lost significantly more weight than controls (−1.6 vs 0.7 kg, 95% CIs not reported) over 12 weeks of extended contact that involved both text messages and face-to-face group sessions. The magnitude of change observed in this trial is also congruent with the intervention effects summarized in two recent meta-analyses of extended contact interventions [12,13] delivered via other modalities (ie, not text messaging).

The GHSH intervention was designed to follow on from a telephone coaching program, in which participants developed a rapport with a health coach. It is positive to note that a semiautomated text message program (with two brief telephone contacts) maintained the perception of accountability and that most participants felt personal engagement with their coach. It is encouraging that participants updated their text message preferences throughout the trial, given that continued engagement is a known facilitator of maintenance [12]. Particularly encouraging was that this highly tailored contact was achieved at a relatively low cost, which supports the scalability of GHSH.

Strengths

Strengths of this trial include: the range of outcomes evaluated to inform service delivery; the high retention rate (216/228, 95%); its conduct in partnership with the service delivery agents and funders; and, the rigorous research design embedded within real-world delivery [38]. In line with public health principles and how the GHS is delivered, all participants were recruited and analyzed in this trial regardless of whether they complied with national guidelines at baseline, strengthening the findings further. These strengths enabled trial findings to inform the uptake of GHSH as part of standard delivery of the GHS program. Future evaluation of the GHSH impact once implemented into practice will advance our understanding of its uptake and the outcomes that can be achieved when scaled up for population-wide delivery.

Limitations

While self-report of anthropometric outcomes was a limitation, the measures showed acceptable validity against objective measures in a GHS subsample [25]. The study was adequately powered for some but not all outcomes. The differences between trial participants and others completing GHS during the recruitment period may indicate the types of groups willing to receive a text message-delivered intervention, but may also reflect biases in research participation and eligibility criteria. This comparison of the trial sample to graduating GHS users is appropriate given this is the intended audience of the extended contact program; however, it is also useful to consider whether GHS users are broadly representative of Australian adults. Previous evaluations [39] have shown that GHS users were representative in relation to education, employment status, Aboriginal status, and fruit and vegetable consumption, but there was a disproportionately high representation of women, which may be expected given evidence of their higher likelihood to access health advice and attempt to lose weight compared with men. In the current trial, there was minimal missing data from the baseline and 6-month data collection points. Our sensitivity analysis using multiple imputation showed that missing data had very minimal impact on the interpretation of our findings.

Conclusions

The GHSH extended contact intervention was feasible to deliver, acceptable to GHS clients and led to significantly better outcomes than standard practice in weight loss and physical activity. Supporting individuals to maintain positive lifestyle changes through cost-effective programs is paramount to the success of the GHS and more broadly to public health in Australia.

Acknowledgments

We would like to acknowledge the participants, GHS coaches, Medibank Health Solutions staff and GHSH project staff. This trial was funded by the New South Wales Ministry of Health and an Early Career Researcher grant from The University of Queensland.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Confounders considered and adjusted for in main and sensitivity analyses.

[PDF File (Adobe PDF File), 49KB - mhealth_v4i2e42_app1.pdf]

Multimedia Appendix 2

Odds of being in the ‘Get Healthy, Stay Healthy’ (GHSH) trial (n=228) within those completing the Get Healthy Service (GHS) during the GHSH trial recruitment period (n=1071).

[PDF File (Adobe PDF File), 47KB - mhealth_v4i2e42_app2.pdf]

Multimedia Appendix 3

Characteristics of ‘Get Healthy, Stay Healthy’ (GHSH) trial participants at baseline with and without missing data

[PDF File (Adobe PDF File), 53KB - mhealth_v4i2e42_app3.pdf]

Multimedia Appendix 4

Mean changes within the ‘Get Healthy, Stay Healthy’ (GHSH) intervention group (I; n=114) and the control group (C; n=114) using multiple imputation for missing data.

[PDF File (Adobe PDF File), 103KB - mhealth_v4i2e42_app4.pdf]

Multimedia Appendix 5

CONSORT-EHEALTH Checklist.

[PDF File (Adobe PDF File), 924KB - mhealth_v4i2e42_app5.pdf]

Multimedia Appendix 6

CONSORT-EHEALTH Checklist.

[PDF File (Adobe PDF File), 924KB - mhealth_v4i2e42_app6.pdf]

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Abbreviations

BMI: body mass index
CATI: computer-assisted telephone interview

CI: confidence interval
CPM: counts per minute
FFBQ: Fat and Fiber Behavior Questionnaire
GEE: generalized estimation equations
GHS: Get Healthy Information and Coaching Service
GHSH: 'Get Healthy, Stay Healthy'
MDI: minimum differences of interest
MVPA: moderate-vigorous physical activity
SEIFA: Socioeconomic Indexes for Areas
SD: standard deviation

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Review

Text Messaging-Based Interventions for Smoking Cessation: A Systematic Review and Meta-Analysis

Lori A. J Scott-Sheldon[1,2,3], PhD; Ryan Lantini[1], MA; Ernestine G Jennings[1,2], PhD; Herpreet Thind[1], PhD; Rochelle K Rosen[1,3], PhD; Elena Salmoirago-Blotcher[1,4,5], MD, PhD; Beth C Bock[1,2,3], PhD

[1]Centers for Behavioral and Preventive Medicine, The Miriam Hospital, Providence, RI, United States

[2]Department of Psychiatry and Human Behavior, Alpert School of Medicine, Brown University, Providence, RI, United States

[3]Department of Behavioral and Social Sciences, Brown School of Public Health, Providence, RI, United States

[4]Department of Medicine, Alpert School of Medicine, Brown University, Providence, RI, United States

[5]Department of Epidemiology, Brown School of Public Health, Providence, RI, United States

Corresponding Author:
Lori A. J Scott-Sheldon, PhD
Centers for Behavioral and Preventive Medicine
The Miriam Hospital
CORO Building, Suite 309
164 Summit Avenue
Providence, RI, 02906
United States
Phone: 1 401 793 8714
Fax: 1 401 793 8059
Email: lori_scott-sheldon@brown.edu

Abstract

Background: Tobacco use is one of the leading preventable global health problems producing nearly 6 million smoking-related deaths per year. Interventions delivered via text messaging (short message service, SMS) may increase access to educational and support services that promote smoking cessation across diverse populations.

Objective: The purpose of this meta-analysis is to (1) evaluate the efficacy of text messaging interventions on smoking outcomes, (2) determine the robustness of the evidence, and (3) identify moderators of intervention efficacy.

Methods: Electronic bibliographic databases were searched for records with relevant key terms. Studies were included if they used a randomized controlled trial (RCT) to examine a text messaging intervention focusing on smoking cessation. Raters coded sample and design characteristics, and intervention content. Summary effect sizes, using random-effects models, were calculated and potential moderators were examined.

Results: The meta-analysis included 20 manuscripts with 22 interventions (N=15,593; 8128 (54%) women; mean age=29) from 10 countries. Smokers who received a text messaging intervention were more likely to abstain from smoking relative to controls across a number of measures of smoking abstinence including 7-day point prevalence (odds ratio (OR)=1.38, 95% confidence interval (CI)=1.22, 1.55, k=16) and continuous abstinence (OR=1.63, 95% CI=1.19, 2.24, k=7). Text messaging interventions were also more successful in reducing cigarette consumption relative to controls (d_+=0.14, 95% CI=0.05, 0.23, k=9). The effect size estimates were biased when participants who were lost to follow-up were excluded from the analyses. Cumulative meta-analysis using the 18 studies (k=19) measuring abstinence revealed that the benefits of using text message interventions were established only after only five RCTs (k=5) involving 8383 smokers (OR=1.39, 95% CI=1.15, 1.67, P<.001). The inclusion of the subsequent 13 RCTs (k=14) with 6870 smokers did not change the established efficacy of text message interventions for smoking abstinence (OR=1.37, 95% CI=1.25, 1.51, P<.001). Smoking abstinence rates were stronger when text messaging interventions (1) were conducted in Asia, North America, or Europe, (2) sampled fewer women, and (3) recruited participants via the Internet.

Conclusions: The evidence for the efficacy of text messaging interventions to reduce smoking behavior is well-established. Using text messaging to support quitting behavior, and ultimately long-term smoking abstinence, should be a public health priority.

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KEYWORDS

text messaging; smoking cessation; intervention; cigarette smoking; meta-analysis

Introduction

Tobacco use is a major preventable public health problem resulting in nearly 6 million deaths from direct tobacco use and second-hand exposure per year [1]. The global economic cost associated with tobacco use is estimated to be over US$1 trillion annually.[2] In the United States alone, tobacco use causes more than 480,000 deaths each year and costs nearly US$300 billion in health care and productivity losses annually [3,4]. The global burden of tobacco use could be reduced if all smokers had access to smoking cessation programs.

The life expectancy of a smoker is shortened by approximately one decade compared with those who have never smoked; however, smokers who quit before the age of 40 can reduce their risk of smoking-related death by 90% [5]. An estimated 90% of smokers attempt to quit (unsuccessfully) without assistance, even though effective evidence-based behavioral smoking treatments are available [6,7]. Numerous barriers exist to accessing traditional in-person treatments including costs, time commitments, and other logistics such as travel and appointment scheduling [8]. New smoking cessation intervention delivery systems that have the capacity to reach smokers effectively and efficiently are urgently needed [9]. Mobile technology offers an innovative way to reach smokers worldwide.

Mobile broadband reaches nearly one-half of the world's population, and mobile phone text messaging (short message service, SMS) interventions are used by approximately 75% of adults [10]. Thus, text messaging holds great promise as a tool for delivering behavioral interventions that have the ability to reach the vast majority of the population. Interventions delivered through text messaging have been shown to be cost effective [11], and eliminate many barriers to accessing traditional treatments. Text message interventions also offer a variety of advantages. For example, users can also access text messaging services whenever a need exists, and these interventions can be provided to individuals within their own environment and delivered in real-time. The content and timing of messages can be tailored to the individual, enabling the provision of adapted advice and support from evidence-based interventions for smoking cessation, for example, to meet the unique needs of each patient. For these reasons, the design, development, and evaluation of text message-delivered interventions for health promotion, disease prevention, and disease management has greatly increased over the past decade [12].

The use of mHealth is a rapidly expanding area of research and practice [13-18]. Prior reviews of the literature have largely focused on mHealth technologies including text messaging and mobile phone apps, for health promotion, disease prevention, or disease management more broadly; with smoking cessation being one of a number of outcome behaviors [13,18-22]. Three meta-analytic reviews have specifically examined the efficacy of text messaging for smoking cessation [23-25]. Whittaker et al [23] included four randomized controlled trials (RCTs) that involved text messaging [26-29]. Two of the four interventions exclusively used text messages and showed a significant increase in short-term (≤6 weeks) smoking cessation rates relative to controls (risk ratio (RR)=2.18, 95% confidence interval (CI) 1.80-2.65). The other two interventions used a combination of both text messaging and Internet components and showed significant increases in long-term (≤52 weeks) smoking cessation rates (RR=2.03, 95% CI 1.40-2.94). In an updated meta-analysis of mobile phone-delivered interventions (predominately text messaging interventions), Whittaker et al [24] included five RCTs (2 of these studies were included in their previous review) assessing smoking cessation outcomes at longer assessment intervals (ie, ≥6 months) [28-32]. They found that mobile phone interventions resulted in greater smoking cessation rates relative to controls (RR=1.71, 95% CI 1.47-1.99). Most recently, Spohr et al [25] evaluated 13 RCTs assessing text messaging for smoking cessation. Consistent with prior reviews, Spohr et al [25] found text messaging interventions to be more successful at increasing smoking cessation rates relative to control conditions (OR=1.35, 95% CI=1.23, 1.48). Spohr et al [25] also assessed potential moderators of smoking cessation (eg, follow-up length, message frequency), but none of these intervention features moderated the effect of text messaging on smoking cessation. Thus, text messaging interventions have proven to be successful at increasing smoking cessation, but likely due to the small number of studies evaluated, meta-analyses conducted to date have likely been underpowered to detect moderators of text messaging [33]. Thus, important factors (eg, number of text messages) that may strengthen or weaken the efficacy of text messaging interventions remains unknown.

The purpose of this systematic review and meta-analysis is to evaluate the current evidence for text messaging smoking interventions. Our review updates and extends the scope of the prior meta-analytic reviews in five ways. First, we update the prior meta-analytic reviews by including seven RCTs that were omitted from prior reviews. Second, because excluding participants who are lost to follow-up from the analyses may bias effect size (ES) estimates (cf., [34]), we examine differences in the overall ESs based on an intent-to-treat approach and a complete case analysis. Third, we used cumulative random-effects meta-analytic approaches to assess the accumulated evidence for text messaging interventions. Fourth, we assess a broader range of smoking outcomes (eg, number of cigarettes used, nicotine dependence), in addition to smoking abstinence. Finally, we identify the extent to which sample characteristics (eg, gender, age, or geographic region) as well as intervention features (eg, number of text messages sent) moderate the efficacy of text messaging interventions on smoking outcomes.

Methods

Overview

This systematic review and meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [35]. The PRISMA checklist can be found in Multimedia Appendix 1.

Eligibility Criteria

Studies were included if they (1) examined an individual-level text messaging intervention to promote smoking cessation, (2) used a RCT design, (3) assessed smoking outcomes (eg, abstinence, quit attempt), (4) provided sufficient statistical information to calculate ESs, and (5) were available (including electronic publications and dissertations) by December 31, 2014. Studies that examined text messaging interventions with the goal of maintaining (vs initiating) smoking abstinence among recently quit smokers were excluded (eg, Snuggs, McRobbie [36]).

Information Sources and Search Strategy

Multiple electronic reference databases (*PubMed* (1946+), *PsycINFO* (1872+), *ProQuest Dissertations and Theses Full Text* (1973+), *CINAHL* (1981+), *Global Health* (1973+), *The Cochrane Library* (1992+), *Communication & Mass Media Complete* (1915+), and *EMBASE* (1947+)) were searched using a Boolean search strategy: (tobacco OR smok*) AND (text messag*) OR (cellular phones) OR (cell AND phone) OR (mobile) OR (mobile devices) OR ("short message service") or ("multimedia messaging service") AND (interven* or prevent*). Because many electronic databases have specific search methods (eg, Medical Subject Heading (MeSH) terms used in *PubMED* are not used in other databases such as *PsycINFO*), our basic search strategy was modified to accommodate the specific search parameters for each electronic database. No language restrictions were applied. The electronic reference database searches were initially conducted in April 2014 and updated in January 2015 to ensure that we retrieved all available studies through December 31, 2014. Reference sections of relevant manuscripts (including published reviews obtained through the electronic reference database searches) were also reviewed. Finally, we searched the tables of contents of relevant journals (*Journal of Medical Internet Research*; *Telemedicine & eHealth*) for relevant papers.

Study Selection

Study titles and abstracts were initially screened for possible inclusion. Full-text manuscripts of potentially relevant records and references from relevant manuscripts were retrieved and reviewed for final inclusion. Studies that fulfilled the inclusion criteria (see Eligibility Criteria) were included. When authors reported details, ancillary information (eg, results from a pilot study), and/or study information across multiple manuscripts, those manuscripts were linked in the database and represented as a single unit and the manuscript reporting the most complete study sample was selected as the primary manuscript.

Coding and Reliability

Two of three independent coders (LAJSS, RCL, or EGJ) extracted study information (eg, publication year), sample characteristics (eg, gender, ethnicity), design specifics (eg, recruitment method), intervention procedures (eg, number and frequency of text messages), and components (eg, personalized feedback, goal setting) from each study. Methodological quality was assessed using 14 items adapted from validated measures [37,38]. Interrater reliability was assessed for all study, sample, and methodological variables. For the categorical variables, raters agreed on a mean of 79% of the judgments (mean Cohen's κ =.60). Reliability for the continuous variables yielded an average intraclass correlation coefficient (ρ) of 0.89 across categories (median=0.99). Disagreements between pairs of coders were resolved through discussion.

Study Outcomes

Study outcomes included dichotomous (eg, frequencies) and continuous (eg, means) assessments of smoking cessation including abstinence, quit attempts, and cigarette use. Smoking abstinence was assessed using a number of methods including point prevalence abstinence (ie, abstinence from a specific time-point to follow-up assessment), continuous abstinence (ie, abstinence from quit date to follow-up assessment), prolonged or sustained abstinence (ie, sustained abstinence between two assessments), and repeated point prevalence abstinence (ie, abstinence from at least two specific time-points to follow-up assessments; see Hughes et al [39] for details regarding smoking abstinence definitions). Other measures included making a quit attempt and the quantity of cigarettes smoked per day or week. Finally, we assessed nicotine dependence, which was measured using validated measures (eg, Heaviness of Smoking Index [40]).

Effect Size Calculations

ESs were calculated for each study by two of the three independent coders (LAJSS and HT or EGJ). Because the studies assessed smoking outcomes using dichotomous (eg, abstinence) and continuous (eg, quantity of cigarettes smoked per week or month) variables, we used two ES indices to represent the outcomes. For dichotomous outcomes, we estimated a summary odds ratio from 2 × 2 tables by calculating the odds ratio and transforming it to a log OR (with the corresponding standard error) [41]. For continuous outcomes, ESs were calculated using the standardized mean difference [42]. In the absence of means and standard deviations (SD), other statistical information (eg, *F* test) was used [33,43]. ESs (Cohen's d) were corrected for sample size bias [44].

Multiple ESs were calculated from individual studies when the study included multiple intervention conditions (2 studies), measured more than one outcome (18 studies), used (or provided sufficient data to calculate) more than one statistical method to analyze the outcomes (ie, intent-to-treat and complete-case analysis; 19 studies), or assessed outcomes at multiple follow-ups (5 studies). ESs calculated for each intervention were treated as separate studies to avoid violating the assumption of independence [33,43]. Positive ESs indicated that participants who received the text messaging intervention reported higher

smoking abstinence rates, more quit attempts, smoked fewer cigarettes per day or week, and scored lower on measures of nicotine dependence compared with a control or comparison condition. All ESs were reviewed for accuracy; discrepancies were resolved through discussion and final calculations.

Statistical Analyses

ESs were analyzed separately by smoking outcome and stratified by type of analysis (ie, intent-to-treat or complete case analysis). The overall ES for smoking abstinence using standard and cumulative meta-analytic approaches was also assessed (a cumulative meta-analysis provides an updated pooled ES estimate each time a new trial is added). Because smoking abstinence was measured using a number of methods (point prevalence, continuous abstinence, prolonged or sustained abstinence, and repeated point prevalence), only a single measure from each study was included to avoid violating the assumption of independence [43]. Decisions regarding which ES to include for each intervention were based on the most commonly reported measure (ie, 7-day point prevalence), followed by the next common measure, and so forth until all studies reporting an abstinence measure were represented. Two studies (k=3) did not include measures of smoking abstinence [45,46].

Summary ESs were calculated using random-effects procedures such that ES were weighted by the inverse of their random-effects variance [33,47]. The homogeneity statistic, Q, was calculated; a significant Q indicates a lack of homogeneity and an inference of heterogeneity. The I^2 index and the corresponding 95% CIs were also calculated to assess the observed dispersion [48-50] The I^2 index ranges from 0% to 100% with 25%, 50%, and 75%, considered low, moderate, and high levels, respectively, of observed variance reflecting true differences in ESs [51]. Analyses were conducted in Comprehensive Meta-analysis [52] and Stata [53] using publicly available macros [33].

Moderator Analyses

Moderator analyses examined the overall effects of smoking abstinence using a modified weighted least squares regression analyses or the meta-analytic analogue of an analysis of the variance (ANOVA) with weights equivalent to the inverse of the variance plus the random variance component for each ES [33,54,55]. Random-effects models (methods of moment) were estimated. Analyses examined a priori determined moderators of smoking abstinence. Sample and methodological characteristics (eg, gender, age, region, recruitment method), intervention type (text only vs text plus other intervention components), intervention dose and delivery (eg, number of texts sent, frequency of texts), message type (targeted), and intervention content (eg, personalized feedback, goal-setting) were examined. All moderator analyses were conducted in Comprehensive Meta-analysis [52].

Publication Bias

Asymmetries in the distributions of ESs, indicating a possible reporting bias [56], were examined by inspecting funnel plots and assessing the degree of asymmetry [57-59]. As recommended by Stern and colleagues [60], we conducted tests for publication bias only if the dependent variable included 10 or more studies. Trim and fill procedures [61,62] are used to estimate and correct for the possibility of missing studies (based on a rank-based data augmentation procedure) if publication bias is detected using funnel plot asymmetry tests [58,59].

Results

Study Selection

Our search strategy yielded a total of 3678 unique records. Following title and abstract screening, 90 full-text manuscripts were assessed for eligibility. Of these 90 manuscript, 51 were excluded because they did not include a text messaging intervention and/or a control or comparison condition, used a quasiexperimental design, assessed only the maintenance of smoking abstinence (rather than initial smoking cessation), did not measure smoking behavior, or did not provide data suitable for meta-analysis (eg, protocol, qualitative). Our final sample included 20 studies reporting 22 interventions (k) (Figure 1). An additional 19 manuscripts were retained as supplemental information for the included studies (details of the 20 studies included in the meta-analysis are provided in Table 1).

Study Details

The characteristics of the studies, samples, and interventions included in the meta-analysis are described below. Full details are provided in Table 2.

Figure 1. Study retrieval and selection.

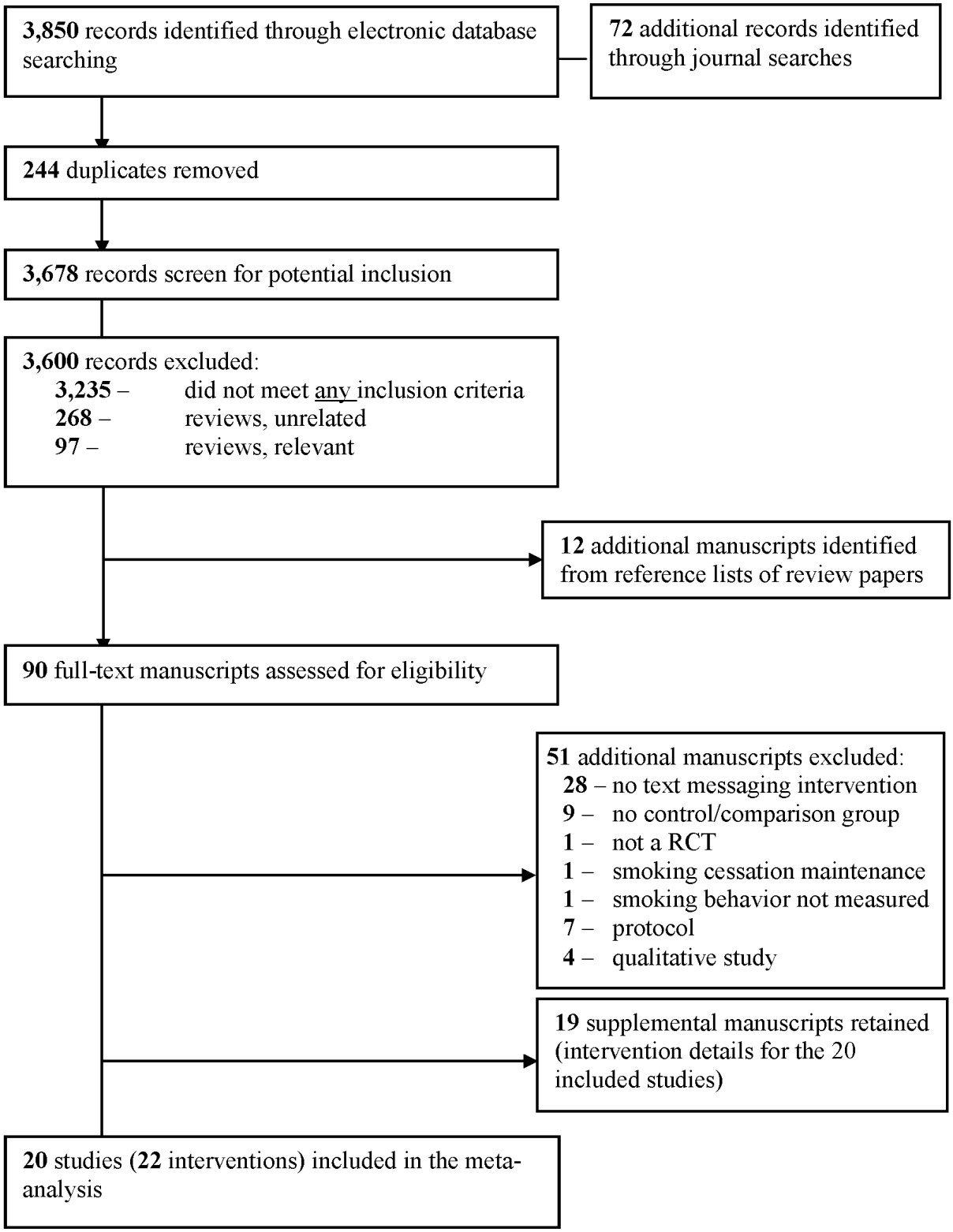

Table 1. The study, sample, and intervention characteristics for the 20 studies (22 interventions) included in the meta-analysis

Citation	Sample	Location & Recruitment	Control	Intervention	Delivery	Texts[a]	Frequency	Flow[b]	Outcomes
Abroms [63]	N[c]=503; 66% F[d]; 79% W[e]; 36 years[f]	USA; internet search engine ads	RCNM[g]	Text2Quit	Text+[h]	45	Decreasing	2	7-day PP[i] 30-day PP[h] repeat PP[j]
Bock [64]; Linked Studies [65]	N=60; 58% F; 65% W; 31 years	Providence, RI; community	ICM[k]	Txt2Quit	Text+	154	Varied	2	24-hour PP 7-day PP ND[l]
Borland [32][m]; Linked Studies [66]	N=1963; 60% F; 42 years	Australia; quitline contacts, internet ads, and cold-contacts from marketing and social research data company	Info	Quit on Q	Text[n]	193	Varied; user-selected	2	7-day PP prolonged abstinence
Borland [32][m]; Linked Studies [66]	N=1963; 60% F; 42 years	Australia; quitline contacts, internet ads, and cold-contacts from marketing and social research data company	Info	Quit on Q & QuitCoach	Text+	193	Varied; user-selected	2	7-day PP prolonged abstinence
Brendryen and Kraft [27]; Linked Studies [67,68]	N=396; 50% F; 36 years	Norway; internet newspaper ads	RCNM	Happy Ending	Text+	189	Varied	2	7-day PP repeat PP
Brendryen [26]; Linked Studies[27]	N=290; 50% F; 40 years	Norway; internet newspaper ads	RCNM	Happy Ending	Text+	189	Varied	2	7-day PP repeat PP
Buller [69]; Linked Studies [32]	N=102; 51% F; 74% W; 25 years	USA; internet social media and search engine ads	RCNM	OnQ	Text	108	Varied; user-selected	2	24-hour PP 30-day PP continuous abstinence quit attempt
Free [30]; Linked Studies [11,70-73]	N=5792; 45% F; 89% W; 37 years	United Kingdom; internet and community ads	ICNM[o]	Txt2stop	Text	225	Decreasing	2	7-day PP 28-day PP continuous abstinence[j]
Free [28]	N=200; 37% F; 36 years	United Kingdom; community ads	ICNM[o]	Txt2stop	Text	225	Decreasing	2	7-day PP[j] 28-day PP[j]
Haug [74]	N=174; 57% F; 25 years	Germany; university	AO[p]	SMS-Coach (one weekly SMS feedback)	Text	14	Low (≤1/week, fixed-dose)	2	Quit attempt CPD[q]
Haug [74]	N=174; 57% F; 25 years	Germany; university	AO	SMS-Coach (three weekly SMS feedback)	Text	42	High (>1/week, fixed-dose)	2	Quit attempt CPD
Haug [45]; Linked Studies [75-78]	N=755; 52% F; 18 years	Switzerland; vocational schools	AO	SMS-Coach	Text	68	High (>1/week, fixed-dose); Decreasing	2	7-day PP 4-week PP CPD

Citation	Sample	Location & Recruitment	Control	Intervention	Delivery	Texts[a]	Frequency	Flow[b]	Outcomes
Mason [46]	N=72; 43% F; 91% B[r]; 16 years	Richmond, VA; respondent driven sampling starting from a substance abuse clinic	ICM	NR[s]	Text	30	High (>1×/week, fixed-dose)	2	CPD
Naughton [79]; Linked Studies [80]	N=602; 53% F; 98% W; 42 years	England; clinics	RCNM	iQuit	Text+	108	Varied	2	continuous abstinence[j] prolonged abstinence
Naughton [81]	N=198; 100% F; 100% W; 27 years	England; clinics	RCNM	MiQuit	Text+	80	Decreasing; varied	2	7-day PP[j] 28-day PP quit attempt
Pollak [82]	N=31; 100% F; 49% W; 28 years	USA; clinic	RCNM	NR	Text	280	High (>1×/week, fixed-dose)	2	7-day PP[j] CPD
Rodgers [29]; Linked Studies [83]	N=1705; 59% F; 25 years	New Zealand; internet and community ads	ICNM	NR	Text	238	Decreasing	2	7-day PP continuous abstinence CPD ND
Shi [84]	N=179; 5% F; 17 years	China; vocational schools	RCNM	NR	Text+	217	Varied	2	7-day PP 30-day PP CPD ND
Skov-Ettrup [85]; Linked Studies [86]	N=2,030; 59% F; 19 years	Denmark; newly registered users of smoking cessation website	RCM[t]	NR	Text+	80	Varied	1	30-day PP
Whittaker [31]; Linked Studies [87]	N=226; 47% F; 27 years	New Zealand; internet and community ads	ICNM	STUB IT	Text+	136	Varied	2	7-day PP continuous abstinence[j] quit attempt
Ybarra [88]; Linked Studies [89,90]	N=151; 39% F; 36 years	Ankara, Turkey; community ads and in-person outreach in local malls	RCNM	SMS-Turkey	Text	119	Varied	1	7-day PP 30-day PP continuous abstinence[j] CPD

Citation	Sample	Location & Recruitment	Control	Intervention	Delivery	Texts[a]	Frequency	Flow[b]	Outcomes
Ybarra [91]; Linked Studies [88,92]	N=164; 44% F; 65% W; 22 years	USA; internet ads	RCM	SMS-USA	Text+	150	Varied	2	7-day PP continuous abstinence[j] CPD

[a]Estimated maximum number of texts a participant could receive.

[b]One-way (1) or two-way (2) text messaging.

[c]Number of participants who began the study.

[d]Proportion female.

[e]Proportion White.

[f]Mean age in years.

[g]Relevant content, not time-matched.

[h]Text messaging plus other electronic delivery formats (eg, emails).

[i]Point prevalence.

[j]Biochemical or collateral verification of abstinence.

[k]Irrelevant content, time-matched.

[l]Nicotine dependence;

[m]The QuitCoach (n=809) and Choice (n=758) arms were excluded because participants did not (or may not have) received smoking-related text messages.

[n]Text messaging alone.

[o]Irrelevant content, not time-matched.

[p]Assessment only control.

[q]Cigarettes per day/week.

[r]Proportion Black

[s]Not reported.

[t]Relevant content, time-matched.

Table 2. Description of study, sample, and intervention characteristics of 20 included studies.

Characteristic	Variable	Summary Statistic
Study		
	Publication year, median (range)	2013 (2005-2015)
	Data collection year, median (range)	2009 (2004-2013)
Sample		
Demographics		
	Sample size, initial/final	15,593/12,477
	Women, mean % (SD[a])	54 (20)
	Age, mean (SD)	29 (8)
	Race, mean % White (SD), k[b]=9	69 (29)
Region of sample, k (%)		
	Europe	9 (45)
	North America	6 (30)
	Oceania	3 (15)
	Asia	2 (10)
Methods		
Recruitment method, k		
	Web-based	6 (30%)
	Offline	8 (40%)
	Web-based and offline	6 (30%)
Enrollment Procedures, k (%)		
	Electronic	6 (30%)
	Phone	1 (5%)
	In-person	5 (25%)
	Multiple	8 (40%)
Study design, k (%)		
	Random assignment of groups	2 (10)
	Matching then random assignment	8 (40)
	True randomization	10 (50)
	Treatment standardized	20 (100)
Pre- and post-test, k (%)		
	Pretest post-test design	20 (100)
Follow-up rate, k (%)		
	85%-100% completed	9 (45)
	70%-84% completed	6 (30)
	<70% completed	5 (25)
Follow-up length, k (%)		
	6 months or longer	3 (15)
	3-5 months	3 (15)
	Less than 3 months	14 (70)
Retention, k (%)		
	Withdrawal/drop-outs reported	20 (100)

Characteristic	Variable	Summary Statistic
	Attrition, cases lost to follow-up considered	20 (100)
Data collection, k (%)		
	Anonymous	1 (5)
	Collateral verification	1 (5)
	Used objective measures (≥50% cases)	7 (35)
	Independent/double-blinding	11 (55)
Data treatment, k (%)		
	Intent-to-treat, reported and used	20 (100)
Data analyses, k (%)		
	Appropriate for the study design	2 (10)
	Controlled for baseline/other covariates	18 (90)
Single versus multiple site study design, k (%)		
	Multisite, replication at ≥2 sites	0 (0)
Intervention		
	Theory used to guide research, k (%)	19 (86)
	Intervention duration (days), median (range)	87 (5-378)
Intervention delivery, k (%)		
	Text messages	11 (50)
	Text messages + other delivery format	11 (50)
	Text messages sent, median (range)	140 (14-280)
Frequency of text messages, k[c]		
	Low (<1/week), fixed-dose	1
	High (>1/week), fixed-dose	4
	Decreasing	6
	Varied	13
	User selected	3
Communication flow, k (%)		
	One-way texts	2 (9)
	Two-way texts	20 (91)
Other Intervention Content (k=11)		
	N sessions, median (range)	2 (1-232)
Other Intervention Delivery, k[c]		
	In-person	2
	Facilitated by computer/technology	1
	Computer/technology	6
	Print materials	2
	Phone	4
Tailored and Targeted Intervention		
	Intervention content tailored	21 (95)
	Intervention content targeted	16 (73)
Other Intervention Content, k (%)		
	Decisional balance exercise	12 (55)

Characteristic	Variable	Summary Statistic
	Personalized feedback	16 (73)
	Self-efficacy	20 (91)
	Self-management skills	22 (100)
	Goal-setting/harm prevention plans	19 (86)
Counseling provided, k (%)[c]		
	In-person	1 (5)
	Phone/voice	3 (14)
	Computer	3 (14)
Social support, k (%)		
	Any	12 (55)
	Individual	11
	Group	1
Biomedical intervention, k (%)		
	Any	9 (41)
	Recommended	7
	Provided	2
Treatment fidelity, k (%)		
		15 (68)
Controls		
Type of control, k (%)		
	WL/NT/AO[d]	2 (10)
	Irrelevant content, time-matched	2 (10)
	Irrelevant content, not time-matched	4 (20)
	Relevant content, time-matched	2 (10)
	Relevant content, not time-matched	10 (50)
Control delivery, k (%)		
	Text messages	6 (33)
	Text messages + other delivery format	4 (22)
	Other delivery format	8 (44)

[a]Standard deviation.

[b]Number of studies.

[c]Multiple categories were possible.

[d]Wait-list/no treatment/assessment only control.

Study and Sample Characteristics

Studies were published (or indexed as an advance online publication) in journals between 2005 and 2015 (median publication year=2013) with data collection occurring an average of 3 years earlier (median data collection year=2009; range, 2004-2013). (All studies available through December 31, 2014 were included in the meta-analysis but one study indexed as an advance online publication was subsequently published during the preparation of this manuscript [46].) Participants were recruited using multiple methods including web-based (eg, Internet advertisements, quitlines (6/20, 30%)), offline (eg, clinics, schools or universities; (8/20, 40%)), or a combination of web-based and offline approaches (eg, internet and community advertisements; (6/20, 30%)). The study samples were located in 10 countries: United States (6), United Kingdom (4), Germany (1), New Zealand (2), Norway (2), Turkey (1), Australia (1), China (1), Denmark (1), and Switzerland (1). Of the 15,593 smokers who consented to participate in the studies, more than one-half were women (8128/15,593, 54%), most were White (mean=69%, SD=0.29), and averaged 29 years of age (range=16-42). The mean retention rate was 78% (SD=0.17).

Control Conditions

The interventions were most often compared with an active comparison condition (18/20, 90%). Many of the active

comparison conditions included smoking-related content (12/18, 67%) but were infrequently matched for time and contact (4/20, 22%). The active comparison conditions included content not delivered via text messaging (8/20, 44%), text messaging (6/20, 33%), and text messaging plus other components (4/20, 22%).

Text Messaging Interventions

Most text messaging interventions were guided by theory (19/22, 86%). Of the 22 interventions evaluated, 59% (13/22) reported using more than one theory to guide the intervention development. A wide range of theories were reported but most often included the Transtheoretical model [93] (11/22, 50%), Social Cognitive Theory [94] (10/22, 45%), and cognitive behavioral therapy [95,96] (5/22, 23%).

Interventions were delivered over a median of 87 days (range, 5-378 days) and included texts messages alone (11/22, 50%) or text messaging plus intervention content delivered using another modality (13/22, 50%). The maximum number of texts messages that a smoker could receive averaged 140 (SD=76) across studies and ranged from 14 to 280 messages. The frequency of these text messages was most often varied (13/22, 59%) and two-way communication (20/22, 91%) was typically allowed. Treatment fidelity (ie, receipt of text messages) was assessed in 68% (15/22) of the studies. Of the 11 interventions that supplemented the text messages with other intervention content, most were delivered entirely via computer/Internet (eg, online chat rooms, smoking-related modules available via the study website; 6/11; 36%) and included a median of two sessions (range, 1-232; k=7).

Most text messaging interventions were targeted (16/22, 73%) to the sample (eg, pregnant smokers) and tailored (21/22, 95%) to the recipient (eg, quit date set by the individual smoker). The interventions often provided personalized feedback on smoking behaviors (16/22, 73%), encouraged participants to set quit goals or make plans to reduce smoking (19/22, 86%), addressed self-efficacy to reach smoking cessation goals (20/22, 91%), and provided self-management skills training (22/22, 100%). Participants were often encouraged to use social support (12/22, 55%) and 41% (9/22) provided or recommended pharmacological interventions (eg, nicotine patch) to aid in their smoking cessation.

Methodological Quality

Studies satisfied an average of 65% (SD=0.09) of the methodological quality criteria, indicating moderate methodological quality. All studies used a RCT, standardized the intervention content (ie, using an intervention manual, facilitator training), and measured smoking behaviors at baseline. Most studies included a follow-up assessment that was administered less than 3 months post-intervention (14/20, 70%) and retained at least 85% (17/20) of the study participants at the final post-intervention assessment (9/20, 45%). Studies rarely obtained collateral verification (1/20, 5%) or used objective measures in at least one-half of the sample (eg, verification of smoking behaviors by testing levels of cotinine or carbon monoxide; 7/20, 35%) to validate self-report measures of smoking cessation. Because most studies personalized text-messages participants received, anonymity could not be ensured (19/20, 95%). Many studies (11/20, 55%) used study personnel who were blind to the group assignment. Studies reported participant flow (ie, withdrawals and attrition; 20/20, 100%). Statistical analyses often controlled for baseline or other characteristics (18/20, 90%) and all studies (20/20, 100%) used an intent-to-treat approach. The proportion of methodological quality that satisfied the criteria was not associated with overall smoking abstinence, B=0.44 (SE=0.45), P=.327, Q_R=0.07, P=.789.

Efficacy of Text Messaging Interventions by Smoking Outcomes

Overview of the Results

Because only five studies assessed smoking cessation at multiple post-intervention assessments [32,46,64,69,91], we used the last post-intervention assessment from each study in the analyses. All studies included post-intervention assessments of smoking cessation including 18 studies (k=19) that measured abstinence (2: 24-hour point prevalence; 14 (k=15): 7-day point prevalence; 9: 4-week point prevalence; 7 continuous abstinence; 2 (k=3) prolonged or sustained abstinence; 3: repeated point prevalence abstinence), 4 studies (k=5) measured quit attempts any time during the intervention period, 8 studies (k=9) assessed cigarette consumption, and 3 studies assessed nicotine dependence. (The summary ESs and homogeneity analyses by smoking cessation measures and type of analysis are presented in Table 3).

Table 3. Summary effect sizes and homogeneity statistics (random effects assumptions) at the final post-intervention assessment for smoking abstinence and quit attempts.

Analyses	Outcome	k[a]	OR[b] (95% CI[c])	Q[d]	*P* Value	I^{2e} (95% CI)
Intent-to-Treat						
	Point prevalence, 24 hours	2	2.60 (1.26, 5.37)	0.14	.704	0 (0, 100)
	Point prevalence, 7 days	16	1.38 (1.22, 1.55)	18.34	.245	18 (0, 55)
	Point prevalence, 30 days	9	1.52 (1.34, 1.71)	5.72	.678	0 (0, 63)
	Continuous abstinence	7	1.63 (1.19, 2.24)	11.31	.079	47 (0, 78)
	Prolonged abstinence	3	1.57 (1.19, 2.08)	0.80	.671	0 (0, 89)
	Repeated point prevalence	3	2.33 (1.61, 3.38)	1.52	.467	0 (0, 58)
	Quit attempt	5	1.15 (0.84, 1.57)	4.35	.360	8 (0, 47)
Complete case						
	Point prevalence, 24 hours	2	3.62 (1.46, 8.99)	0.02	.895	0 (0, 100)
	Point prevalence, 7 days	15	1.43 (1.31, 1.56)	13.55	.484	0 (0, 0)
	Point prevalence, 30 days	9	1.57 (1.39, 1.77)	7.47	.487	0 (0, 100)
	Continuous abstinence	7	1.92 (1.55, 2.38)	6.88	.332	13 (0, 56)
	Prolonged abstinence	3	1.57 (1.19, 2.07)	0.45	.798	0 (0, 95)
	Repeated point prevalence	3	2.33 (1.60, 3.39)	1.41	.495	0 (0, 57)
	Quit attempt	5	1.33 (0.83, 2.13)	4.72	.317	15 (0, 60)

[a]Number of interventions

[b]Odds ratios; greater than 1 indicate that the estimated effects favor the text messaging interventions relative to controls.

[c]confidence interval.

[d]Homogeneity statistic.

[e]Consistency of effect sizes.

Smoking Abstinence

Smokers who received a text messaging intervention were more likely to abstain from smoking relative to controls across a number of smoking abstinence measures (point prevalence, continuous abstinence, prolonged abstinence, and repeated point prevalence). The magnitudes of the summary ESs were larger when complete case analyses were used (see Table 3).

Quit Attempts

Quit attempts were measured at the post-intervention in five studies. There were no differences in quit attempts between text messaging and control groups using intent-to-treat or complete case analyses.

Cigarette Consumption

The number of cigarettes smoked per day or week was measured in eight studies (k=9; 6 complete case, 3 intent-to-treat). Smokers who received a text messaging intervention reported smoking fewer cigarettes per day or week compared with controls, $d_{+random}$=0.17, 95% CI=0.07, 0.28 (complete case analysis). The hypothesis of homogeneity was supported: Q_5=5.89, *P*=.317, I^2=15 (0, 60). There were no significant differences between the intervention and control groups using an intent-to-treat approach ($d_{+random}$=0.07, 95% CI=−0.17, 0.31, Q_2=2.28, *P*=.320, I^2=12, 95% CI=0, 53). The overall analyses (k=9) indicated that participants reported smoking significantly fewer cigarettes per day or week if they received a text messaging intervention versus a control condition: $d_{+random}$=0.14, 95% CI=0.05, 0.23. The hypothesis of homogeneity was supported for cigarette consumption: Q_8=8.60, *P*=.377; I^2=7 (95% CI=0, 45).

Nicotine Dependence

Nicotine dependence was assessed in three studies using a complete case analysis (none of the studies supplied enough information for intent-to-treat analyses for nicotine dependence). There were no significant differences between the intervention and control groups on nicotine dependence at the post-intervention assessment: $d_{+random}$=0.00, 95% CI=−0.39, 0.39, Q_2=7.67, *P*=.022, I^2=74, 95% CI=13, 92).

Standard and Cumulative Analyses of Smoking Abstinence

The overall summary ES for smoking abstinence was significant, OR=1.37 (95% CI=1.25, 1.51; k=19). That is, participants who received a text messaging intervention were 1.37 times more likely to abstain from smoking relative to controls. The hypothesis of homogeneity was supported: Q_{18}=19.36, *P*=.370. I^2 was 7% (95% CI 0, 42). The confidence intervals surrounding I^2 did not exceed the 50% threshold indicating that the proportion of observed heterogeneity is low (a forest plot of the overall smoking abstinence is provided in Figure 2).

The cumulative meta-analysis was performed using the final completion date for data collection for each study (Figure 3). Results showed that the benefits of using a text messaging approach for smoking cessation was established by 2009 (end of data collection for Free et al [30]), after only five RCTs involving 8383 smokers (OR=1.39, 95% CI=1.15, 1.67, P<.001). Results from the additional 13 studies (k=14) with 6870 participants did not change the established efficacy of text messaging interventions for smoking cessation. The CIs surrounding the ES estimates narrowed as the data accumulated.

Exploratory analyses restricted to the 10 studies that were of moderate to high methodological quality (ie, studies satisfying at least 65% of the methodological quality criteria; median=70%, range, 65%-80%) also indicated that the efficacy of text messaging for smoking cessation was established by 2009 (end of data collection for Free et al [30]), after only three moderate to high quality studies involving 6388 smokers, OR=1.46, 95% CI=1.29, 1.64. A cumulative plot for smoking abstinence restricted to studies meeting criteria for moderate to high methodology quality is provided (Figure 4).

Figure 2. Forest plot of the overall odds ratio and the corresponding 95% confidence intervals for smoking abstinence. The size of the square representing the odds ratio for each study is proportional to its weight in the analysis.

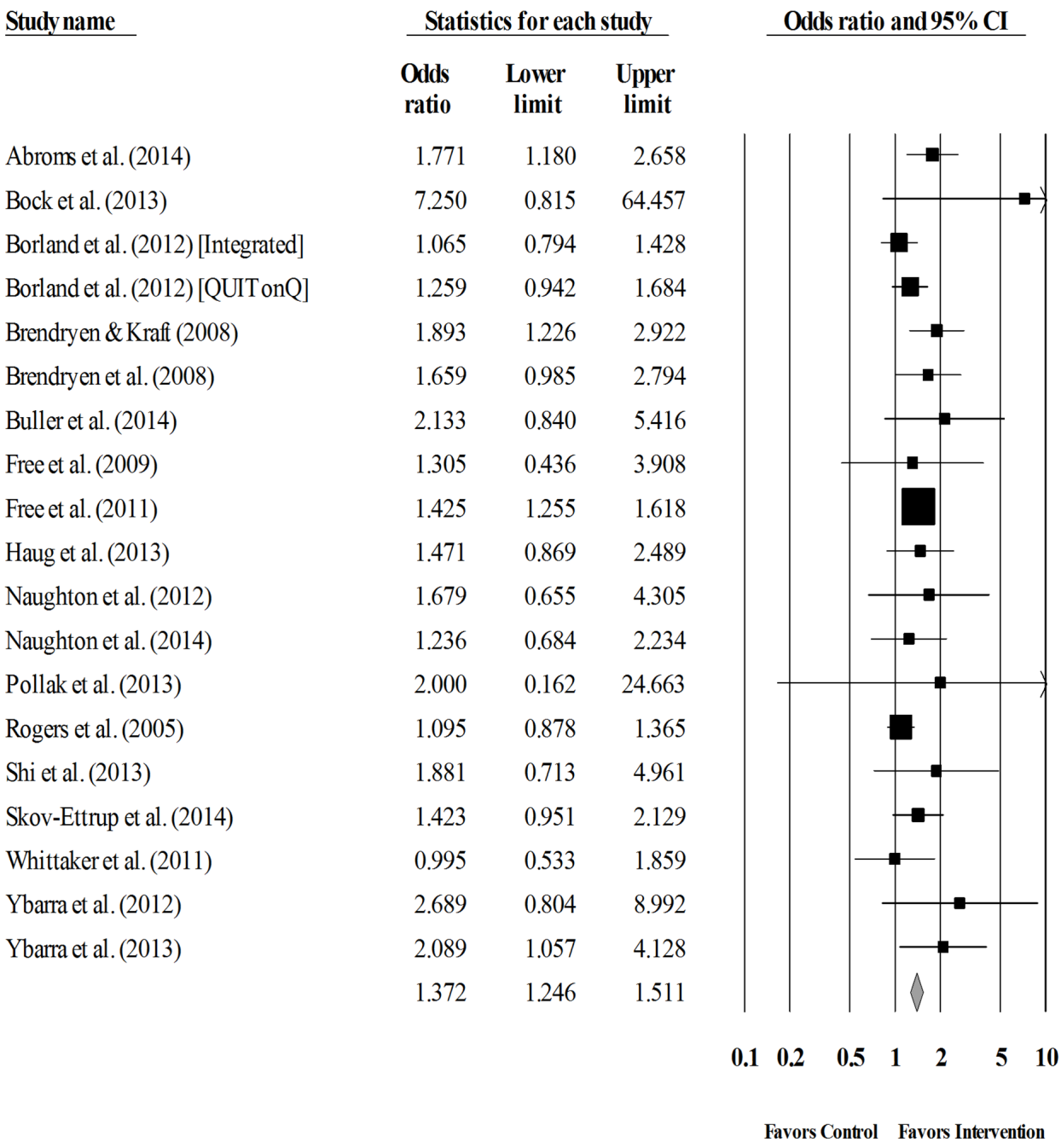

Figure 3. Cumulative plot of the overall weighted mean effect sizes and the corresponding 95% confidence intervals for smoking abstinence, based on final date of data collection.

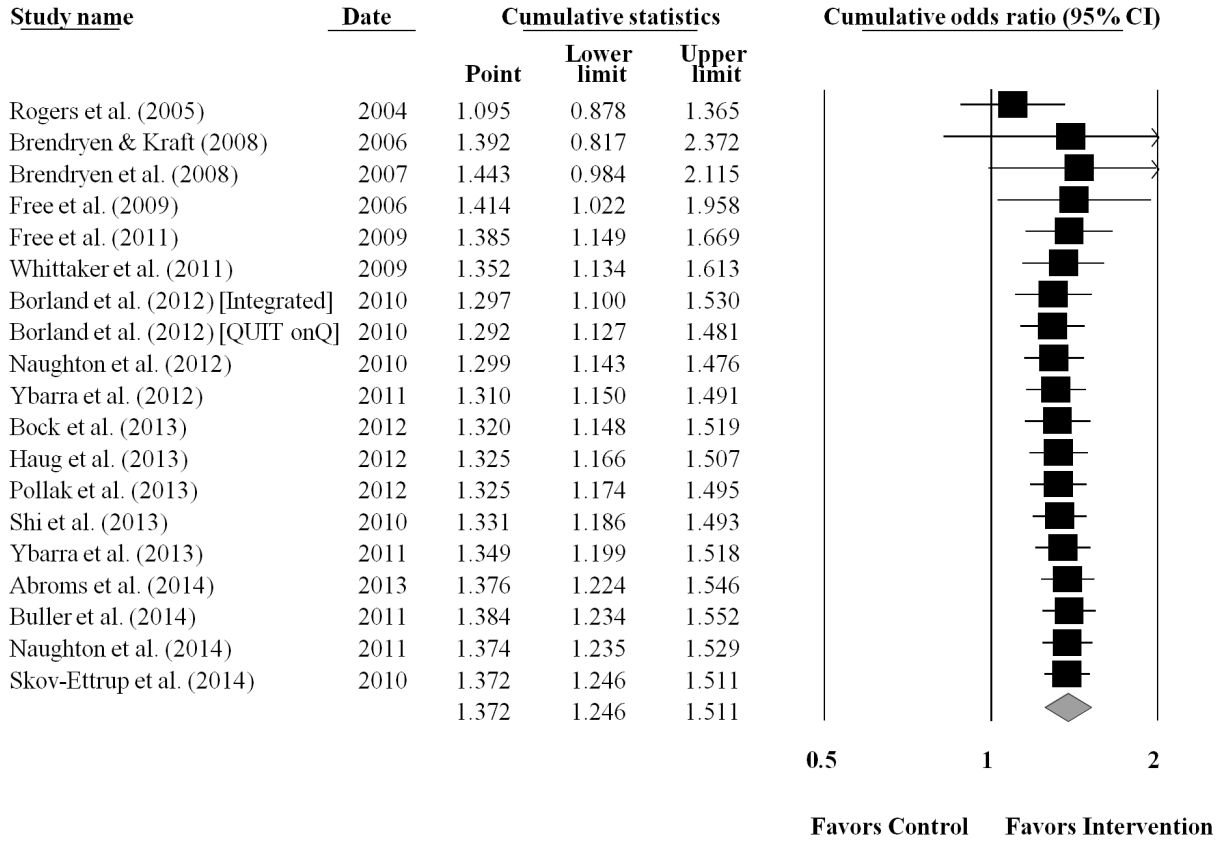

Figure 4. Cumulative plot of the overall weighted mean effect sizes and the corresponding 95% confidence intervals for smoking abstinence, based on final date of data collection and restricted to studies with moderate to high methodological quality ratings.

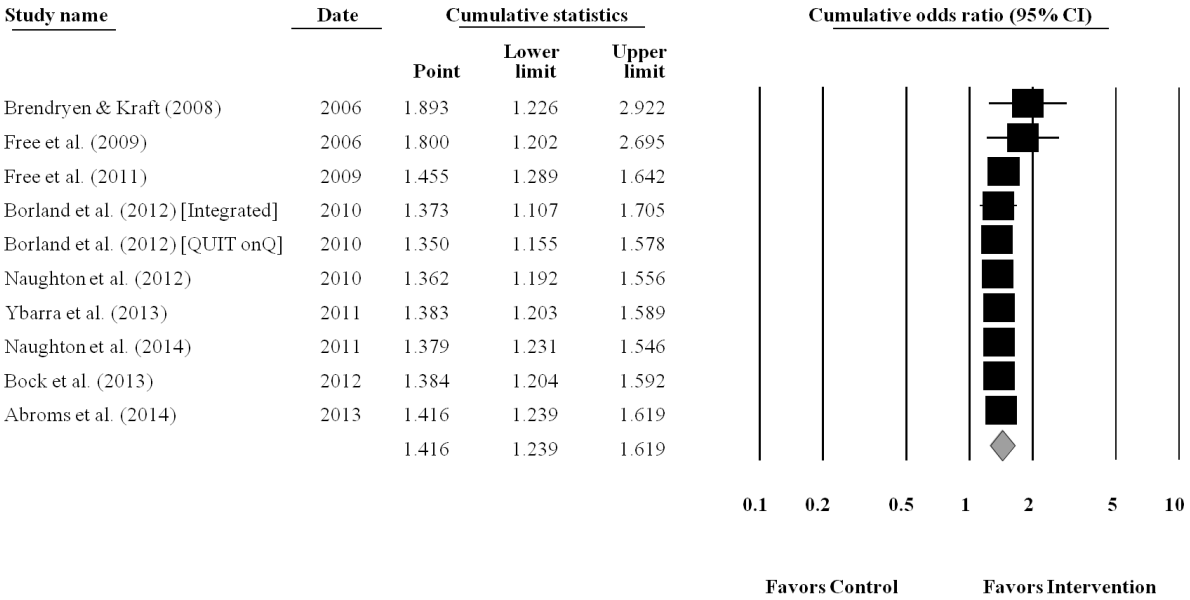

Table 4. Moderators of overall smoking abstinence at the final available assessment.[a]

Characteristics	Moderators	k[b]	B (SE)	OR[c] (95% CI[d])	Q_B[e]
Sample					
	Women, %	19	0.58 (0.26)*		1.07
	Mean Age	19	0.39 (0.24)		0.10
Region of Sample					14.38**
	Europe	8		1.46 (1.31, 1.62)	
	North America	5		1.94 (1.41, 2.67)	
	Oceania	4		1.12 (0.97, 1.30)	
	Asia	2		2.16 (1.02, 4.61)	
Methods					
	Methodological quality rating	19	0.44 (0.45)		0.07
Recruitment					6.39*
	Web-based	6		1.72 (1.41, 2.11)	
	Offline	6		1.45 (1.05, 2.00)	
	Web-based and offline	7		1.30 (1.18, 1.43)	
Intervention					
	Intervention duration, no. days	19	0.21 (0.09)*		1.48
Intervention type					0.67
	Text	8		1.33 (1.17, 1.52)	
	Text+	11		1.45 (1.23, 1.70)	
	Text messages, n sent	19	0.54 (0.16)***		2.24
Frequency of texts					0.10
	Varied	13		1.40 (1.20, 1.64)	
	Other	6		1.36 (1.17, 1.57)	
Communication flow					0.27
	One-way	2		1.53 (1.02, 2.28)	
	Two-way	17		1.37 (1.23, 1.52)	
Intervention targeted					2.06
	Yes	15		1.41 (1.28, 1.55)	
	No	4		1.20 (0.98, 1.47)	
Provided counseling					3.41
	Yes	3		1.85 (1.33, 2.58)	
	No	16		1.34 (1.23, 1.46)	
Decisional balance exercise					0.09
	Yes	9		1.41 (1.18, 1.69)	
	No	10		1.36 (1.20, 1.55)	
Personalized feedback					0.00
	Yes	13		1.38 (1.23, 1.54)	
	No	6		1.39 (1.07, 1.80)	
Self-efficacy addressed					0.09
	Yes	17		1.37 (1.24, 1.52)	
	No	2		1.49 (0.88, 2.54)	

Characteristics	Moderators	k[b]	B (SE)	OR[c] (95% CI[d])	Q_B[e]
Social support					0.89
	Yes	11		1.42 (1.26, 1.59)	
	No	8		1.28 (1.07, 1.53)	
Biomedical intervention					0.71
	Yes	9		1.42 (1.25, 1.60)	
	No	10		1.30 (1.11, 1.53)	
Active control					2.37
	Yes	16		1.42 (1.29, 1.55)	
	No	3		1.20 (0.99, 1.45)	

[a]Meta-regression (continuous variables) and the meta-analytic analogue to the ANOVA (categorical variables) homogeneity analysis were conducted to examine potential moderators of smoking abstinence. All moderator tests are based on random-effects models.

[b]Number of interventions.

[c]Summary odds ratio.

[d]confidence interval.

[e]Homogeneity test for between-groups.
*P<.05; **P<.01; ***P<.001.

Moderators of Smoking Abstinence

Moderator tests were conducted for overall smoking abstinence (Table 4). Compared with controls, text messaging interventions were more successful in increasing smoking abstinence when the trials included fewer women (B=0.58, SE=0.26, P=.025) and were conducted in Asia (OR=2.16, 95% CI=1.02, 4.61), North America (OR=1.94, 95% CI=1.41, 2.67), or Europe (OR=1.46, 95% CI=1.31, 1.62) versus Oceania (OR=1.12, 95% CI=0.97, 1.30), Q_3=14.38, P=.002. Text messaging interventions were more successful at increasing smoking abstinence when the participants were recruited via the Internet (eg, Web-based advertisements, quitline; OR=1.72, 95% CI=1.41, 2.11) versus offline (eg, schools or clinics; OR=1.45, 95% CI=1.05, 2.00) or via a combination of Web-based and offline approaches (eg, Internet and community ads; OR=1.30, 95% CI=1.18, 1.43), Q_2=6.39, P=.041.

Risk of Publication Bias

Both graphical and statistical tools were used to test for the possibility of publication bias. Results from Begg's test [58] and Egger's regression asymmetry test [59] revealed no evidence of publication bias for the dependent variables with sufficient cases for assessment (ie, 7-day point prevalence abstinence and overall smoking abstinence). The funnel plots and results of the statistical tests are available in Multimedia Appendix 2.

Discussion

Primary Findings

This meta-analysis evaluated the impact of text messaging interventions on smoking outcomes among 20 RCTs reporting on 22 interventions among 15,593 smokers. The results of this meta-analysis provide evidence for the efficacy of text messaging interventions on smoking outcomes. The overall odds of smoking abstinence were 1.37 times higher in the text messaging versus control or comparison groups. This finding is comparable to other meta-analyses evaluating text messaging interventions for smoking cessation [23-25]. Furthermore, our cumulative meta-analysis showed that the benefits of text messaging interventions for smoking cessation were established by 2009, after only five RCTs involving 8383 smokers and culminating with Free et al [30], although the results of the trial were not published until 2011. Most of the subsequent RCTs were already underway or completed by 2011. The robustness of this finding (coupled with limited evidence of heterogeneity) clearly indicates that conducting any future RCTs with the primary goal of assessing the efficacy of text messaging for smoking cessation is unnecessary.

It is noteworthy that the summary ESs favored the treatment groups even when 90% (18/20) of the controlled trials used an active control and 67% (12/18) of these active controls included some smoking-related content. These active controls with smoking-related content used a variety of means to disseminate smoking cessation information including smoke-free websites, self-help guidebooks, and smartphone apps. Some of the active controls included in the overall smoking abstinence analyses also provided text messaging, but the text messaging was a weaker form of that offered to the intervention groups or contained unrelated content (eg, diet and physical activity, importance of study participation). For example, Pollak et al [82] compared text messaging support messages that used a scheduled, gradual smoking reduction approach with standard smoking-related text messaging support messages and Free et al [30] compared smoking-related text messages with study-related participation texts (eg, thanking participants for taking part in the study, requests for updating contact details). Further probing revealed that the use of an active comparison condition with or without text messaging did not moderate smoking abstinence (active comparisons with any text messages: OR=1.37, 95% CI=1.17, 1.61, k=8; active comparisons without text messages: OR=1.39, 95% CI=1.18, 1.64, k=10; Q_1=0.02, P=.897). Furthermore, there was no difference between active

comparisons that included smoking-related (OR=1.55, 95% CI=1.02, 2.38, k=3) or nonsmoking (OR=1.35, 95% CI=1.10, 1.66, k=5) text messaging, Q_1=0.38, *P*=.561. Thus, our meta-analysis provides evidence that text messaging interventions for smoking cessation improves smoking abstinence above and beyond other (weaker) smoking cessation delivery modalities with or without text messaging.

Our meta-analysis also demonstrated that the magnitudes of the summary ESs across measures of smoking abstinence were weaker in text messaging studies using an intent-to-treat analytic approach versus a complete case analysis (ORs ranged from 1.38-2.60 vs 1.43-3.62). Excluding participants after randomization from analyses introduces bias that may alter the conclusions made about individual studies' treatment effects [34]. Failure to account for these biases can also affect meta-analytic results. Future studies should include intent-to-treat analyses when presenting their results to minimize potential biases, and perhaps make efforts to examine patterns of attrition.

The results from our moderator analyses revealed three important moderators of text messaging interventions for smoking cessation. First, text messaging interventions conducted in North America, Europe, and Asia produced better results than those conducted in Oceania. All of the RCTs located in North America were conducted in the United States Over the past 20 years, smoking has become far less socially acceptable in the Unites States than in previous decades [97]. Smoking is no longer permitted in government offices and other government facilities, and in most of the Unites States smoking is not permitted in restaurants and many other public venues [98]. Smoke-free laws are also in place in many European Union countries, and many countries represented in this study have completely banned smoking in public places, workplaces, or on public transportation [99]. Smoke-free environments have also been introduced in many Asian countries such as China and Turkey [100,101]. It may be that light-touch/low-intensity interventions such as text messaging are most effective when the surrounding environment supports cessation, or at least is actively unsupportive of continued smoking.

Second, the efficacy of the text messaging interventions for smoking cessation differed by men and women. That is, studies with larger proportions of women participants were less successful at improving smoking abstinence. Prior research has suggested that interventions to increase smoking cessation may be less effective for women than men [102]. Women may be less likely than men to quit smoking for a number of reasons including weight concerns, less social support for quitting, genetic variants that affect the efficacy of pharmacotherapies, and mood regulation [103]. Interventions that specifically address women's concerns can help women stop smoking [104]. Only two text messaging interventions included in this meta-analysis were targeted to women, specifically pregnant smokers, and found mixed results [81,82]. One study found no differences in smoking abstinence between the text messaging intervention and no message control group, while the other study showed a significant difference in smoking abstinence among women who received text messages that used a scheduled gradual smoking reduction approach versus support text messages alone. Future text messaging interventions for smoking cessation should address the specific treatment needs of women with further attention to the type and intensity of the text messages desired by women smokers.

Finally, recruitment method was associated with increases in smoking abstinence. Studies in which participants were recruited exclusively via the Internet achieved higher rates of smoking abstinence relative to studies that recruited participants using an offline or combination of Web-based and offline recruitment methods. It may be that Web-based recruitment is more culturally consistent with use of a technology-delivered intervention, and individuals who respond to Web-based recruitment may be more comfortable with and better able to respond to a text-message delivered program compared with other individuals. More work is needed to identify the characteristics of individuals who do well with technology-delivered interventions versus those who would respond better to more traditional (eg, in-person) therapies.

Prior research comparing four Web-based (3: health risk assessment; advertisements; quit line screening) and offline (1: offline materials such as television advertisements) recruitment methods also showed that Web-based advertisements had higher yield rates and were more cost-effective than other approaches [105]. Despite the potential benefits of Web-based recruitment, other research shows that participants recruited via the Internet (vs offline) communication are less likely to participate through follow-up [106]. Retention rates for studies using Web-based, offline, and combined recruitment methods in this meta-analysis were 70%, 83%, and 78%, respectively. Retaining smokers in smoking cessation interventions is an ongoing concern but these concerns may be mitigated by the added convenience, potential participation rates, and cost-effectiveness of Web-based recruitment. Nonetheless, text messaging interventions for smoking cessation should employ strategies known to be effective for increasing retention (eg, emphasizing the benefits of participation, reminders [107]) when recruiting smokers via the Internet.

Limitations

Several limitations should be considered when interpreting our findings. One limitation of evaluating the effect of smoking cessation interventions is that studies used many different measures (eg, variety of measures of abstinence such as point prevalence and continuous abstinence; for a discussion, see [39]). Because some of these measures (eg, repeated point prevalence) were used in a limited number of studies, we could not assess moderators of these individual types of measures separately and necessitated pooling measures for our overall analyses. Second, evaluation of this literature is also limited as few of these studies systematically assessed the additive effect of text messaging. That is, most of the text messaging interventions included text messaging plus some other smoking-related content (eg, counseling, supporting website) rather than testing the effects of the same smoking cessation intervention with or without text messaging. Future studies should examine the additive effects of text messaging plus other smoking-related content. Third, identification and retrieval of

relevant studies may have been hindered by the author's use of keywords (eg, failure to include 'intervention' as a keyword because the intervention modality was the focal point of the study). To reduce the possibility of inadvertently missing studies, we searched multiple electronic databases, tables of contents of relevant journals, and reference sections of relevant papers and reviews [108]. Fourth, we focused our analyses on the final post-intervention assessment because most of the studies (15/20, 75%) did not provide data from multiple post-intervention assessments. Using the last post-intervention assessment as the point of analysis provides a stronger test of the potential effects of the intervention on long-term cessation because initial intervention effects tend to decay over time (cf. Johnson et al [109]). In this meta-analysis, however, the final post-intervention assessment occurred most often immediately following the completion of the intervention (median=1 week; range, 0-44 weeks). Future research with follow-up periods extended to 1 year or longer is needed to determine whether reductions in smoking behavior are sustained over time. Finally, our moderator tests were limited to the available data. Potentially important moderators could not be tested because there were too few or too many cases to be evaluated (eg, 22/22, 100% of the interventions provided self-management training), and thus were omitted from our analyses.

Conclusion

The prevalence of cigarette smoking has declined over the past decade; however, more than 1 billion adults continue to smoke worldwide [1]. Text message interventions to reduce tobacco use have the promise to reach a wider audience with minimal cost and fewer resources. The current meta-analytic review provides unequivocal support for the efficacy of text messaging interventions for smoking abstinence. Future research should be directed to understanding for whom and under what circumstances text messaging interventions are optimized, and the duration of the effects.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

PRISMA Checklist.

[PDF File (Adobe PDF File), 249KB - mhealth_v4i2e49_app1.pdf]

Multimedia Appendix 2

Publication Bias.

[PDF File (Adobe PDF File), 195KB - mhealth_v4i2e49_app2.pdf]

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Abbreviations

ANOVA: analysis of the variance
AO: assessment only
CPD: cigarettes per day/week
CI: confidence interval
ES: effect size
ICM: irrelevant content, time-matched
ICNM: irrelevant content, not time-matched
NR: not reported
ND: nicotine dependence
OR: odds ratio
PP: point prevalence
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized control trial
RCNM: relevant content, not time-matched
RCM: relevant content, time-matched
RR: risk ratios
SD: standard deviation
SMS: short message service
Q: homogeneity statistic

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Original Paper

Bilingual Text4Walking Food Service Employee Intervention Pilot Study

Susan Weber Buchholz[1], PhD, RN, FAANP; Diana Ingram[1], MPH, PhD; JoEllen Wilbur[1], PhD, RN, FAAN; Louis Fogg[1], PhD; Giselle Sandi[2], PhD; Angela Moss[1], MSN, ANP-BC, RN; Edith V Ocampo[1], MS

[1]Rush University, College of Nursing, Chicago, IL, United States

[2]Rush University, Academic Affairs, Chicago, IL, United States

Corresponding Author:
Susan Weber Buchholz, PhD, RN, FAANP
Rush University, College of Nursing
600 S. Paulina Street 1030D
Chicago, IL,
United States
Phone: 1 312 563 3590
Fax: 1 312 942 3038
Email: susan_buchholz@rush.edu

Abstract

Background: Half of all adults in the United States do not meet the level of recommended aerobic physical activity. Physical activity interventions are now being conducted in the workplace. Accessible technology, in the form of widespread usage of cell phones and text messaging, is available for promoting physical activity.

Objective: The purposes of this study, which was conducted in the workplace, were to determine (1) the feasibility of implementing a bilingual 12-week Text4Walking intervention and (2) the effect of the Text4Walking intervention on change in physical activity and health status in a food service employee population.

Methods: Before conducting the study reported here, the Text4Walking research team developed a database of motivational physical activity text messages in English. Because Hispanic or Latino adults compose one-quarter of all adults employed in the food service industry, the Text4Walking team translated the physical activity text messages into Spanish. This pilot study was guided by the Physical Activity Health Promotion Framework and used a 1-group 12-week pre- and posttest design with food service employees who self-reported as being sedentary. The aim of the study was to increase the number of daily steps over the baseline by 3000 steps. Three physical activity text messages were delivered weekly. In addition, participants received 3 motivational calls during the study.

Results: SPSS version 19.0 and R 3.0 were used to perform the data analysis. There were 33 employees who participated in the study (57.6% female), with a mean age of 43.7 years (SD 8.4). The study included 11 Hispanic or Latino participants, 8 of whom requested that the study be delivered in Spanish. There was a 100% retention rate in the study. At baseline, the participants walked 102 (SD 138) minutes/day (per self-report). This rate increased significantly (P=.008) to 182 (SD 219) minutes/day over the course of the study. The participants had a baseline mean of 10,416 (SD 5097) steps, which also increased significantly (P=.017) to 12,540 (SD 5149). They significantly improved their performance on their aerobic fitness test (P<.001). The participants had a baseline mean systolic blood pressure of 120 mm Hg and diastolic blood pressure of 76 mm Hg, a mean body mass index of 29.29 kg/m2, and a mean waist circumference of 36.95 inches, without significant changes seen at 12 weeks.

Conclusions: We were able to conduct a motivational physical activity text messaging intervention within the workplace setting. Both physical activity and aerobic fitness improved. However, at baseline, participants were more active than they perceived themselves to be. Although there is insufficient evidence to draw strong conclusions about the study findings, it would be useful to test this physical activity text messaging intervention in a sedentary sample within a larger workplace intervention study trial conducted over a longer time frame.

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KEYWORDS

text messaging; physical activity; workplace; employee; Spanish; feasibility; food service

Introduction

Half of all adults in the United States do not meet the level of recommended aerobic physical activity of ≥ 150 minutes/week of moderate-intensity physical activity or ≥ 75 minutes/week of vigorous-intensity physical activity [1,2]. Engaging in the recommended amount of moderate-intensity physical activity contributes to a significantly lower risk of developing chronic diseases [2]. One type of setting that has been used to test different types of physical activity interventions is the workplace [3]. In fact, in the United States, the Centers for Disease Control and Prevention has issued recommendations to be used for implementing physical activity guidelines in the workplace, in part because it is a logical place to implement physical activity interventions [4]. Workplace clinics are now being used to address a variety of health concerns of employees across the income spectrum. Importantly, workplace chronic disease prevention programs are being used to facilitate promotion of employee health [5-7].

Food service workers represent a growing employee sector in the United States, with Hispanic or Latino employees constituting a significant part of this group [8]. As with many workers, food service employees have work schedule constraints that interfere with finding time for routine preventive health behaviors, including physical activity [9]. Many food service workers are low-income wage earners. Household income influences where people live, which, in turn, can define neighborhood environment and walkability [10-12].

With the widespread use of cell phones and text messaging, there is a new generation of technology available for promoting health that may address some of these constraints that are placed on workers. Physical activity is one of the areas of health promotion where promising results are being seen in the form of text messaging intervention research [13-16]. There are now 7 billion cell phones worldwide [17]. In the United States, there are 317 million cell phones [18], and, on average, 81% of cell phone users engage in text messaging. Cell phone use is common across income levels, including among low-income individuals, of whom 84% have a cell phone [19]. Of Americans who use cell phones, Asian Americans text 69% of the time, white non-Hispanics text 79% of the time, black non-Hispanics text 85 % of the time, and Hispanics text 87% of the time [20,21].

To the best of our knowledge, although workplace physical activity interventions have been conducted in the past, no studies that use text messaging with food service workers to increase physical activity have been published [3,13,14]. The purposes of this study were to determine (1) the feasibility (in terms of recruitment, retention, delivery, and satisfaction) of implementing a bilingual 12-week Text4Walking intervention and (2) the effect of the Text4Walking intervention on change in physical activity (self-report questionnaire, accelerometer, aerobic fitness) and health status (blood pressure [BP], body mass index, waist circumference) in a food service employee population.

Methods

Design

This pilot research was conducted using a 1-group 12-week pre- and posttest design.

Setting and Sample

Participants were recruited from a food service company site located in Chicago, Illinois, the United States. At this food service company, nurse practitioners provide preventative, acute, and chronic health care in a workplace clinic. This food service company is a catering facility that prepares food for retail customers and employs an average of 400 employees, depending on the season. The employees at this company work in either nonadministrative positions, including food preparation, transportation, and facilities management, or as part of the administrative team. The majority of the nonadministrative food preparation workers perform their duties in assembly line-like environments where they repetitively prepare the same types of food for the same retail customer. The company is open 24 hours a day, 7 days a week, every day of the year. To effectively recruit participants from each shift, the research team members covered several 4-hour blocks of time during the week at different times of the day.

For the purposes of this pilot study, a sample size of 32 was needed in order to obtain a power of 0.80. This was determined by using an effect size of 0.72 for physical activity obtained by calculating the mean of effect sizes found in a recent physical activity text message systematic review [13]. With a power of .80, given this effect size and a 1-tailed alpha of 0.05, a sample size of 26 was needed. Oversampling by 20% was done because of the possibility of attrition, resulting in a sample size of 32.

Participants were eligible for this study if they met the following inclusion criteria: (1) currently an employee at the study site; (2) aged 30 to 65 years; (3) able to speak and read English and/or Spanish (by self-report); (4) own a cell phone with texting capability; (5) were sedentary, which is self-reporting as engaging in 20 minutes of vigorous or 30 minutes of moderate physical activity <3 times a week [2]; (6) being without a disability that inhibits walking as determined by the PAR-Q (Physical Activity Readiness Questionnaire) & You [22]; and (7) had no major signs or symptoms of pulmonary or cardiovascular disease, or a systolic BP of >160 mm Hg, or a diastolic BP of >100 mm Hg [23,24]. The age range was chosen because physical activity levels decrease as people approach and enter middle age [1]. The researchers were interested in how participants perceived their physical activity levels, therefore choosing to base inclusion criteria on the initial self-report of physical activity, even if baseline data showed more active physical activity levels than reported by the participant initially.

Intervention

Using focus groups, the Text4Walking research team developed a database of motivational physical activity text messages in English [25]. Hispanic or Latino adults compose 16.4% of the total number of employed persons in the United States and 24.8% of all adults who are employed in the food service

industry [8]. Many Hispanic or Latino adults speak Spanish as their primary language [26]. The Text4Walking team translated the physical activity text messages into Spanish and validated those text messages with a Hispanic focus group [27]. This study used both the English and Spanish text messages (see Multimedia Appendix 1).

A Physical Activity Health Promotion Framework adapted from Pender's Health Promotion Model [28] was used to guide the Text4Walking intervention. Physical activity text messages were designed to increase perceived benefits of and to decrease perceived barriers to physical activity. To increase commitment to a plan of action, the researchers asked each participant to take part in a 15-minute individual orientation session provided by bilingual research assistants that included a physical activity prescription and strategies for committing to a plan of action to engage in physical activity.

The 12-week goal for each person was to reach a total of 3000 steps (daily) more than their baseline steps. An increase of this amount approximates to 30 minutes of moderate-intensity physical activity daily. This facilitates an individual's ability to obtain the recommended 150 moderate-intensity physical activity minutes per week [2]. To determine an individualized physical activity prescription, baseline steps were obtained from a pedometer that was taped (no data shown) and worn the week before starting the intervention [29], and a mean of pedometer steps was determined by dividing the days that the pedometer was worn by the total number of steps taken [30]. Each week participants needed to increase their daily step total by 300 steps. Adding 300 daily steps each week to the previous week's goal, over a period of 10 weeks, allowed participants to achieve the goal of adding 3000 daily steps more than their baseline steps. Their weekly goals were written out for them in the form of a physical activity prescription. Participants were provided with an accelerometer to measure their steps throughout the 12 weeks of the study and given instructions on how to wear and use it. Although participants were encouraged to wear their accelerometers every day, there was no way to enforce that.

Text messaging was used to deliver physical activity text messages and to receive step counts from participants. Participants were told that they would receive 3 text messages a week over the following 12 weeks. The decision to send 3 text messages was made based on prior research done by the team, which showed that, overall, participants preferred this number of motivational text messages a week [25]. These physical activity text messages emphasized the benefits received from increasing one's physical activity and provided tips on overcoming barriers to engaging in physical activity.

The participants were given a list of more than 250 text messages [25,27], from which they chose a total of 36. If they preferred, they could write up to 10 of their own text messages and choose from the text message database for the remainder of their text messages. Participants chose the 3 days and the time of day during the week when they wanted to receive their text messages. In addition to receiving the motivational physical activity text message, every morning they received a text message that asked them to reply to that message with the previous day's step count. The research team used a Web-accessible software system that hosted and sent the text messages to participants' cell phones [31].

In addition, participants received 3 motivational calls of 5-10 minutes each during weeks 2, 6, and 10 of the study from 2 master's prepared research team members who had received training and were provided with an instruction manual [29]. The main purposes of these motivational physical activity calls were to encourage participants to increase their number of daily steps and the intensity of their walking and to remind them to report their daily steps via text messages.

Measures

All study questionnaires that were not available in Spanish were translated from English into Spanish by bilingual research team members. They were also reviewed and revised as needed and approved by a certified translator. For the Spanish-speaking participants, a bilingual research team member was available on-site to communicate with them in Spanish.

Feasibility Measures

Recruitment was measured by obtaining the screening rate and eligibility and ineligibility rates at baseline. Retention was assessed by obtaining the dropout rate over 12 weeks. Delivery was measured by obtaining the number of text messages generated over 12 weeks. Delivery was also measured by assessing the number of motivational phone calls that were recorded as delivered in the tracking software used in the study. Satisfaction [32] was measured using the Physical Activity Text Messaging Satisfaction Tool. This is a 6-question dichotomous researcher-developed tool. The items in this tool were analyzed for content validity.

Participant Baseline Personal and Environmental Characteristics

Age, sex, ethnicity, marital status, educational level, size of household, number of children aged less than 18 years, personal and household income, type of job, and the shift worked were collected at baseline for all participants.

The Neighborhood Environment Walkability Scale–Abbreviated (NEWS-A) was used to assess environmental influences of walkability at baseline. Fifteen items from 4 scales in NEWS-A (land use mix–access, street connectivity, infrastructure and safety for walking, and aesthetics) were combined to create an overall targeted walkability score [33]. These items used a Likert scale, 1 (strongly disagree) to 4 (strongly agree), with higher scores indicating high walkability. Test-retest reliability on NEWS-A ranges from 0.58 to 0.80, and criterion validity has been demonstrated [34]. The items used to create the walkability score for this study had a Cronbach alpha of .83.

Physical Activity Outcomes

Physical activity measures were obtained using subjective and objective measures at baseline and 12 weeks, because the researchers were interested in examining both perceived and actual measures of physical activity. Also, both a self-report assessment and an accelerometer-based assessment of physical activity were included in the study because either measure by itself engenders some degree of measurement bias. By including

2 measures, it is possible to obtain some convergent validity [35].

The short International Physical Activity Questionnaire (IPAQ) asked participants about the amount of time they had spent engaged in physical activity in the past 7 days. Seven questions were asked about the days per week and hours and minutes per day spent in vigorous and moderate activity, as well as the amount of time spent walking and sitting, and resulted in walking minutes and moderate and vigorous minutes per day of these activities [36]. Strong reliability has been demonstrated with a Spearman ρ as high as .88, and criterion validity has also been demonstrated [36].

Steps were measured using physical activity monitors. The baseline steps were determined by having participants wear a Kenz Lifecorder e-STEP [37]. The intervention steps were measured during the 12 weeks of the study, using a Lifecorder PLUS [38]. As the researchers were interested in measuring steps taken by participants, both pedometers and accelerometers can be used, as they are reliable tools for estimating the number of steps taken daily [39]. Participants were instructed to wear the accelerometer at their waist during waking hours with instructions to report their step count at the end of each day via text messages. The Lifecorder PLUS recorded time-stamped data, total steps, bout steps, and intensity, for 60 days of data [38]. From this accelerometer wear, we assessed mean daily steps in the 12th week of the study. To be included in the weekly analyses, there had to be ≥10 hours of daily wear time available for 3 or more days during the 12th week. If data were unavailable for that, we accepted data from the 11th week as well. For accelerometer data, an average was taken of the days with acceptable wear time. We also calculated 10-minute bouts of moderate- or vigorous-intensity data [40,41].

To determine aerobic fitness, a 2-minute step test was conducted at baseline and 12 weeks. After warming up, participants marched in place to a minimum knee-stepping height for 2 minutes. This stepping height was individually determined as the level even with the midway point between the iliac crest and the knee [42]. This test is correlated with the Rockport 1-mile walk (r=.75) and has concurrent validity with age [43].

Health Status Outcomes

Blood pressure was measured at baseline and 12 weeks, following the National High Blood Pressure Education Program guidelines [44-46]. Body mass index and waist circumference were assessed at baseline and 12 weeks [47]. Height was measured using a stadiometer and reported to the nearest 0.25 inch. Weight was measured with participants wearing light clothing and no shoes, using a Seca Robusta 813 high capacity digital scale and reported to the nearest 0.20 pound [48]. Waist circumference was measured using a flexible vinyl tape [49].

Data Collection Procedures

The study was approved by the University Institutional Review Board [50]. Initial screening was done in person. A research assistant then scheduled interested employees for further screening, which took place before or after work or during a break at the work site health clinic. Employees could complete this assessment, which took an hour or less, in one visit or in multiple visits. Employees were given further explanation of the study, informed consent was obtained, and they had their height, weight, and BP taken. They also completed an aerobic fitness test. If employees had health problems that would impact modest physical activity, they were referred to the study nurse practitioner who reviewed the findings. If needed, the employee was then referred to the workplace health clinic nurse practitioner or their own health care provider to determine if they were eligible or not for the study [24]. Eligible employees then received the study questionnaires and chose their text messages from the data bank. In addition, they were given a blinded pedometer to wear for 7 days and a date and time to return for their study orientation. The study was conducted over a period of 9 months in 2014.

At the study orientation, participants were given their physical activity prescription based on baseline pedometer findings, instructed that they would receive 3 motivational calls throughout the study, and taught how to use the accelerometer Lifecorder PLUS to obtain their daily steps and text them in response to a text message reminder. They were given a participant manual that provided instructions on using their accelerometer and information on receiving and sending text messages. Participants were asked to return at week 7 to have their accelerometer data downloaded. Fresh batteries were provided as needed, and an appointment time was provided for their 12-week final assessment.

At the end of the 12 weeks the participants returned the study accelerometer and completed study questionnaires and health assessments. At both baseline and 12 weeks, participants were given US $15 for completing the assessment and step test, US $10 for completing the study questionnaires, and a US $15 stipend to compensate them for using their text message cell phone service. As a gift, they were given an Omron HJ-112 Premium Pedometer [51] at the completion of the final assessment.

Data Analysis

All data analyses were performed using SPSS version 19.0 and R 3.0 [40,52]. Because this was a pilot study, any significant findings should be viewed as exploratory. The tables are made up of either means and standard deviations or frequency distributions of the pertinent measures collected in this study. Paired t tests were conducted to examine change over time in the sample. For measures with significant skew, a Friedman's analysis of variance of ranks was also performed.

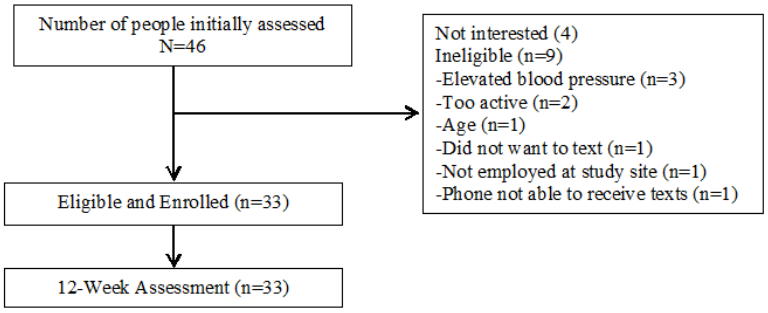
Results

Feasibility

Recruitment and Retention

Over a 3-month time period, 46 employees responded to the recruitment strategies and were screened for eligibility (see Figure 1). Further, 4 of them were not interested, and 9 were not eligible. Enrollment was closed once enough participants were enrolled to obtain the anticipated number needed. At the end of recruitment, a total of 33 eligible employees were enrolled in the study, and they all completed it.

Figure 1. Participant Flow and Study Design of the Text4Walking Intervention with Food Service Employees.



Delivery

A total of 1188 text messages (33 participants × 3 calls/week × 12 weeks) were generated. Five of the 33 participants chose to develop their own messages; 2 of them created 6 messages each, and 3 of them created 10 messages each. In the study, 1152 text messages were sent to the participants, resulting in a 97% expected delivery rate of text messages, and a mean text messaging rate of 2.9 out of a possible 3 text messages per week. A small number of text messages were not delivered because of unreported changes in participant phone numbers. However, a delivery log was checked weekly by the research team, and phone numbers were updated as soon as possible. The 33 participants received a mean of 1.7 out of a possible 3 study calls. Sixty-one percent (20/33) received the week 2 call, 58% (19/33) the week 6 call, and 46% (15/33) the week 10 call. Three attempts were made to reach the participants for each of the study calls. It is unclear why participants chose not to answer telephone calls.

Satisfaction

In general, participants were satisfied with the text message delivery of the intervention. The majority, 91% (30/33), said that they read the text messages. Eighty-eight percent (29/33) thought that 3 text messages a week were the right amount; however, 4 of the participants would have preferred to receive 5 text messages per week. Again, the vast majority (30/33, 91%) thought that the text messages motivated them to increase their physical activity.

Demographics, Cell Phone Use, and Walkability

Eleven participants self-identified as being of Hispanic or Latino ethnicity (see Table 1). Of these 11 participants, 8 asked to have the intervention delivered in Spanish. Personal income for 63.3% (19/33) of the participants was US $39,999 or less. This is below the national US personal income mean of US $44,888 for 2013 [53]. The jobs were approximately evenly divided between administrative (n=15) and nonadministrative positions (n=18). The majority of the participants owned a smart phone (30/33, 90.9%). Of these 30 participants, 56.7% (17/30) owned an Android phone and 40.0% (12/30) owned an iPhone. The walkability score was 2.8, which is between 2 (somewhat disagree that the neighborhood is walkable) and 3 (somewhat agree that the neighborhood is walkable) on the Likert scale used for this score.

Table 1. Participant demographics and walkability.

Characteristics		Total (N=33)
Age in years, mean (SD) (range)		43.7 (8.4) (31-60)
Gender, n		
	Male	14
	Female	19
Ethnicity, n		
	Hispanic or Latino	11
	Not Hispanic or Latino	22
Race, n		
	African American	14
	White	7
	Asian	1
	Unknown	11
Marital status, n		
	Married/living with partner	19
	Widowed/divorced or separated	5
	Single, never married	9
Education, n		
	Some high school or less	8
	Completed high school	10
	Some college or university	10
	Completed college or university	5
Size of household, mean (SD) (range)		3.8 (1.7) (1-7)
Number of children aged <18 years, mean (SD) (range)		1.3 (1.5) (0-4)
Shift, n		
	First shift	27
	Second shift	6
Targeted walkability score, mean (SD) (range)		2.8 (0.3) (1-4)

Physical Activity Behaviors and Health Status

The IPAQ results demonstrated significant increases in walking minutes per day (see Table 2). However, for walking, moderate, and vigorous minutes there were 0-minute scores for some of the participants. For walking minutes, which meant walking for at least 10 minutes, 7 participants reported 0 minutes at week 1, and 5 participants reported 0 minutes at week 12. For moderate minutes, 14 participants reported 0 minutes at week 1, and 6 participants reported 0 minutes at week 12. Finally, for vigorous minutes, 16 participants reported 0 minutes at week 1, and 11 participants reported 0 minutes at week 12.

For physical activity measured with an accelerometer, there was also a significant improvement in steps walked from baseline to 12 weeks. There was significant skew associated with these data, and, as a consequence, we also conducted a Friedman's analysis of variance of ranks. When we did so, the *P* value increased from less than .001 to .07. In our study, the effect size was 0.41 for the accelerometer steps. In addition, participants had a significant improvement in their 2-minute step test, suggesting improved aerobic fitness [43].

The mean baseline BP results of the sample are within acceptable ranges for normal BP (Table 2) [44]. Two-thirds (22/33, 66.7%) of the participants were overweight or obese [1]. The average baseline waist circumference for women was above the recommended 35 inches for women, while the average baseline waist circumference for men was below the recommended 40 inches for men [54].

Table 2. Physical activity and health status.

Physical activity and health status measures	Baseline week 1	12 weeks	Paired *t* test	Degrees of freedom	*P* value
	Mean (SD) (range)	Mean (SD) (range)			
IPAQ[a,b] (N=33)					
Walking minutes (minutes/day, on days walked at least 10 minutes)	101.67 (137.88) (0-480)	182.33 (218.64) (0-660)	2.85	32	.008
Moderate minutes (minutes/day, on days engaged in moderate physical activity)	85.30 (141.52) (0-480)	131.06 (167.62) (0-600)	1.67	32	.105
Vigorous minutes (minutes/day, on days engaged in vigorous physical activity)	64.64 (131.50) (0-540)	137.42 (205.39) (0-705)	1.95	32	.060
	10,416 (5097)	12,540 (5149)			
Steps (N=22)	(3000-19,449)[c]	(2773-24,173)[d]	2.59	21	.017
Intensity data					
Minutes of moderate-to-vigorous physical activity per day in 10-minute bouts (N=31)	—	10.5 (12.5) (0-46.9)	—	—	—
Fitness test (N=33)	87.28 (18.24) (45-123)	96.69 (16.10) (64-121)	4.56	31	<.001
Health status					
Systolic BP[a], mm Hg	120 (12) (99-141)	118 (15) (89-153)	0.96	32	.343
Diastolic BP, mm Hg	76 (10) (57-93)	76 (13) (52-109)	0.24	32	.811
BMI[a], kg/m^2	29.29 (6.43) (20.01-51.71)	29.08 (6.66) (19.26-52.12)	1.50	32	.142
Normal weight (18.5-24.9), n (%)	11 (33.3)	—			—
Overweight (25-29.9), n (%)	8 (24.2)	—			—
Obese I, II, III (>30), n (%)	14 (42.4)	—			—
Waist circumference, inches	36.95 (5.19) (26.75-50.00)	37.27 (5.43) (26.00-48.00)	1.12	32	.273
Female (n=19)	36.36 (4.89) (26.75-46.00)	36.51 (5.19) (26.00-45.50)			—
Female, >35 inches, n (%)	4 (21.1)	4 (21.1)			—
Male (n=14)	37.75 (5.66) (31.00-50.00)	38.30 (5.78) (31.00-48.00)			—
Male, >40 inches, n (%)	4 (28.6)	5 (35.7)			—

[a]IPAQ: International Physical Activity Questionnaire; BP: blood pressure; BMI: body mass index.

[b]IPAQ data had significant skew.

[c]Pedometer data.

[d]Accelerometer data.

Discussion

Principal Findings

The research team was able to obtain participants for the study, and bring them back for their postintervention assessment, in the workplace setting. This may be partially attributed to flexibility in recruiting participants at times that were convenient to them, such as the beginnings and ends of 3 daily work shifts. Furthermore, the intervention appealed to a significant Latino work force because all materials were available in both English and Spanish and intervention research assistants were bilingual. The text messages were successfully delivered, and the participants received these text messages. The participants

expressed satisfaction with the content and frequency of the text messages. This may be attributable to the fact that participants were allowed to choose their own text messages as well as create their own. The successful delivery of physical activity text messaging intervention was based on the Physical Activity Health Promotion Framework. The physical activity text messages were designed to reduce perceived barriers to physical activity and to increase commitment to a plan of action.

The intervention was endorsed by the work site clinic, which is a valued employee benefit at this workplace. All assessments were held in the familiar workplace health clinic setting. Many employees had already established a health care relationship with the nurse practitioners at the workplace health clinic, setting the stage for a health promotion intervention [5-7]. Using workplaces to deliver health promotion interventions is important because participants who might otherwise not enroll in an intervention may do so because of the ease of enrolling at their place of work.

One strength of the study was that, even though participants began with a fairly high baseline step count, they significantly increased their step count by more than 2000 steps during this 12-week intervention. They also significantly increased their daily walking minutes and improved their aerobic fitness. In general, participants tend to overestimate the amount of physical activity they engage in when they self-report [55]. It is likely that this occurred in this study as well because the accelerometer steps were somewhat lower than expected based on the participants' self-reports of physical activity. However, with both measures, participants showed a marked increase in the amount of physical activity from baseline to week 12.

Six studies [56-61] were identified as similar to this study. These six studies examined physical activity as a primary outcome and used text messaging as the only method of motivation for participants. Effect sizes (Cohen's *d*) for these six studies ranged from 0.29 to 0.64, with a mean of 0.42 [62]. These outcomes were similar to the effect size we found in our study.

One paradoxical finding of the study was that participants who described themselves as sedentary were found to be taking more than 10,000 steps a day when activity was measured with an accelerometer. On the basis of the findings of this pilot study, we will add an objective physical measure when recruiting participants for future studies. Therefore, even if participants self-declare as sedentary, we will have the objective data that is necessary to determine if this is in fact the case.

Another strength of the study was allowing the participants to provide individualized input into delivery of the text messages. This included choosing if they wanted the text messages delivered in English or Spanish and the best days of the week and times of day to receive the text messages. Participants also had an opportunity to create their own text messages. Allowing for participant input into delivery of text messages is similar to other successful physical activity text message studies [57,58,60].

Comparison With Prior Work

Participants' mean baseline number of daily steps, 10,416, was considerably higher than the US adult mean of 5117 steps per day [63]. This was despite participants' self-reporting that they did not engage in 20 minutes of vigorous or 30 minutes of moderate physical activity ≥3 times a week. Workplace employees in a food service job quite likely take more steps during the day than the average US adult does, in part owing to the nature of their jobs. Food service employees stand and walk during their work shifts and may cover fairly large distances while walking in a warehouse setting [64].

Future Direction

Future studies should include a larger sample as well as a longer intervention phase followed by a maintenance phase to assess the effectiveness of the intervention. In order to test the effectiveness of this intervention, this study should be done with a sedentary sample, using a control group, and a substantially larger number of participants. The length of the study needs to also be increased. Although other health promotion text messaging studies have demonstrated positive outcomes at 12 weeks [65,66], one study noted that lifestyle behavior changes seen at 3 months were not sustained at 6 months [67]. Therefore, using this physical activity text messaging intervention with a less physically active sample may not in and of itself demonstrate the same level of increase as seen in this group of relatively physically active participants, especially if it is used over a longer period of time. It would also be useful to assess maintenance of physical activity after the intervention has ended [68].

Limitations

The study has several limitations including how physical activity was measured objectively, a potentially biased recruitment process, no control condition, a small sample size, and a modest intervention time frame. Two different physical activity monitors were used at baseline and follow-up steps. Although both monitors are valid for measuring steps, using 2 different monitors may have produced measurement bias. There may have been self-selection bias with more active potential participants volunteering for this small study relative to the size of catchment. Although the researchers intended to recruit a sedentary sample, the actual sample recruited was, on average, an active one. Therefore, it is unknown how an actual sedentary sample would have responded to this intervention. While we were able to retain all of the participants who were recruited, it is possible that the original recruitment process tended to be most successful with the more physically active potential participants. Also, one implication of the no control condition is that it is impossible to determine the impact of text messaging alone in the study.

Although the study had a small sample size, significant findings relative to increased physical activity were discovered [62]. The intervention needs to be further tested with a larger sample using a control condition clinical trial. In addition, although the intervention duration was relatively short (12 weeks), the participants had rather high baseline steps. However, it is unknown if less active adults would increase their physical activity within this same time frame. It is also unknown if the participants in the Text4Walking study would have sustained these results over a longer period of time.

Conclusions

This paper provides the feasibility and preliminary effectiveness data for a research project. We were able to conduct a motivational physical activity text messaging intervention within the workplace setting. Both physical activity and aerobic fitness improved. However, participants were more active objectively than they perceived themselves to be subjectively. When targeting sedentary participants for a physical activity intervention in the future, it will be critical to assess baseline physical activity with an objective measure to ensure that participants who report they are sedentary are actually part of a low physical activity group. Although there is insufficient evidence to draw strong conclusions about the study's findings, it would be useful to test this physical activity text messaging intervention in a larger workplace intervention study trial conducted over a longer time frame, in order to confirm that it is effective at increasing physical activity levels in adults.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Physical Activity Text Messages - English and Spanish - Text4Walking.

[XLS File (Microsoft Excel File), 83KB - mhealth_v4i2e68_app1.xls]

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Abbreviations

BP: blood pressure
IPAQ: International Physical Activity Questionnaire
NEWS-A: Neighborhood Environment Walkability Scale–Abbreviated
PAR-Q: Physical Activity Readiness Questionnaire

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Original Paper

A Pilot Test of Self-Affirmations to Promote Smoking Cessation in a National Smoking Cessation Text Messaging Program

Jennifer M Taber[1], PhD; William M.P Klein[1], PhD; Rebecca A Ferrer[2], PhD; Erik Augustson[1], PhD, MPH; Heather Patrick[3], PhD

[1]Behavioral Research Program, National Cancer Institute, National Institutes of Health, Rockville, MD, United States

[2]Basic Biobehavioral and Psychological Sciences Branch, Behavioral Research Program, National Cancer Institute, National Institutes of Health, Rockville, MD, United States

[3]Applied Behavior Change Science, Envolve PeopleCare, Bethesda, MD, United States

Corresponding Author:
Jennifer M Taber, PhD
Kent State University
Department of Psychological Sciences
309 Kent Hall Annex
Kent, OH, 44242
United States
Phone: 1 1 330 672 8783
Fax: 1 1 330 672 3786
Email: jtaber1@kent.edu

Abstract

Background: Although effective smoking cessation treatments, including mHealth interventions, have been empirically validated and are widely available, smoking relapse is likely. Self-affirmation, a process through which individuals focus on their strengths and behaviors, has been shown to reduce negative effects of self-threats and to promote engagement in healthier behavior.

Objective: To assess the feasibility of incorporating self-affirmations into an existing text messaging-based smoking cessation program (Smokefree TXT) and to determine whether self-affirmation led to greater engagement and higher cessation rates than the standard intervention.

Methods: Data were collected from smokers (n=1261) who subscribed to a free smoking cessation program and met eligibility criteria. The intervention lasted 42 days. The original design was a 2 (Baseline affirmation: 5-item questionnaire present vs absent) × 2 (Integrated affirmation: texts present vs absent) factorial design. Only 17 eligible users completed all *baseline affirmation* questions and these conditions did not influence any outcomes, so we collapsed across baseline affirmation conditions in analysis. In the *integrated affirmation* conditions, affirmations replaced approximately 20% of texts delivering motivational content.

Results: In all, 687 users remained enrolled throughout the 42-day intervention and 81 reported smoking status at day 42. Among initiators (n=1261), self-affirmation did not significantly improve (1) intervention completion, (2) days enrolled, (3) 1-week smoking status, or (4) 6-week smoking status (all Ps>.10); and among the 687 completers, there were no significant effects of affirmation on cessation (Ps>.25). However, among the 81 responders, those who received affirmations were more likely to report cessation at 6 weeks (97.5%; 39 of 40) than those not given affirmations (78.1%; 32 of 41; $\chi^2(1)=7.08$, P=.008).

Conclusion: This proof-of-concept study provides preliminary evidence that self-affirmation can be integrated into existing text-based cessation programs, as the affirmations did not lead to any adverse effects (ie, less engagement or lower rates of cessation). Among those who reported smoking status at the end of the intervention period (6.4% of eligible respondents), affirmations facilitated cessation. This study provides a “proof-of-concept” that brief, low-touch interventions may be integrated into a text messaging program with potential benefits, minimal disruption to the program or users, and little cost. Many questions remain regarding how self-affirmation and similar approaches can promote engagement in population interventions.

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KEYWORDS

self-affirmation; smoking cessation; mHealth; text messaging ; theoretical study; self concept; motivation

Introduction

Effective smoking cessation treatments, including those delivered via mobile health platforms, have been empirically validated and are widely available [1-3]. However, quitting smoking is challenging and relapse is likely [4]. Smokers may feel threatened by temptation to smoke if they perceive an inability to meet cessation challenges. Self-affirmation [5]—or focusing on strengths and values—can offset self-threats and promote healthier behaviors [6-8]. In prior research, self-affirmed smokers took more antismoking brochures and reported greater self-efficacy to quit and higher intentions to reduce smoking [9-10]. When combined with other intervention strategies, self-affirmed undergraduates actually smoked less [11]. Smokers who self-affirm may be more successful at quitting, because temptation may be seen as less threatening to competence or self-control.

Self-affirmation interventions may be scalable and disseminable, as demonstrated elsewhere (eg, education [12]), and given that lasting effects emerge with minimal interventions [13,14]. Self-affirmation operates through recursive, self-perpetuating processes, by motivating individuals to capitalize on preexisting resources to facilitate change [13]. Implementing brief affirmations into at-scale cessation interventions may increase their effectiveness. This study assessed the feasibility of incorporating self-affirmations into an existing text messaging-based smoking cessation program and examined whether self-affirmation might facilitate greater engagement and higher cessation rates than a standard intervention.

Methods

Procedure

Data were collected from smokers who subscribed to a free smoking cessation program, implemented by the US National Cancer Institute (Smokefree TXT; [15]), online or through text. Smokefree TXT (launched in 2009) was designed following a review of text-based cessation programs and input from cessation and mHealth experts. The library has been updated multiple times following user testing and analysis of user data. Taxonomic analysis indicates that the text program provides 35 different behavioral change techniques [16].

Upon enrollment, users of the program reported their mobile number, age, gender, state of residence, and smoking frequency, and were instructed to set a quit date between today and 14 days in the future. Users were informed that the program provided "24/7 encouragement, advice, and tips to help smokers quit smoking and stay quit." As part of the standard program, users received daily text messages designed to improve self-efficacy to quit and to provide motivation. Texts were sent up to 14 days before users' self-selected quit day and during the 42-day period following users' self-selected quit day. Before the quit day, all users received 2-3 texts/day (with the exception of the baseline affirmation prior to enrollment, which consisted of 5 texts). For the first two weeks after quit day, users received 3-4 texts/day. From day 15 to 42, users received 1-3 texts/day. The first text of the day was sent at 9am, followed by 12pm, 3pm, and 6pm, for as many texts as were sent that day. All texts were unique and the order was standardized within each condition. Users could disenroll anytime. With the exception of the self-affirmations, no changes were made to the existing program to modify it for research use. Thus, these data represent an evaluation of incorporating self-affirmation into a readily available, already disseminated intervention.

Users who subscribed during a 6-week period in fall 2014 were automatically enrolled into one of three enhanced intervention conditions based on which day they enrolled. Enrollment into the three conditions was distributed across days of the week and throughout the duration of this 6-week period. Control data were drawn from users who subscribed during 2 weeks in September immediately prior to this 6-week period. The original design was a 2 (Baseline affirmation: 5-item kindness questionnaire present vs absent; adapted from Reed and Aspinwall [17]) × 2 (Integrated affirmation: texts present vs absent) factorial design testing two methods of affirmation (for a total of four conditions). Only 17 eligible users completed all *baseline affirmation* questions and these conditions did not influence any outcomes, so we collapsed across baseline affirmation conditions in analysis. Analytic comparisons were between standard intervention (consisting of the control condition and the baseline affirmation only condition) versus intervention enhanced with self-affirmation integrated throughout the 6-week program (consisting of the integrated affirmation only condition and the integrated plus baseline affirmation condition).

In the *integrated affirmation* conditions (hereafter referred to as "affirmations"), affirmations (which instructed users to focus on strengths or values when feeling threatened or anxious) replaced approximately 20% of texts delivering motivational content. On quit day and the 3 subsequent days, one text was randomly replaced each day. For all subsequent days, every 5th or 6th text was replaced to ensure that the remaining 11 affirmation texts were distributed equally (the last affirmation text was on day 38). The order of administration was constant for all users. Table 1 contains sample texts, created by JMT, WMPK, and RF based on the self-affirmation literature [18], and the motivational texts used in the control condition.

Table 1. Sample affirmation and control texts.

Day text was delivered	Affirmation message content	Control (motivational) message content
Quit day	When you feel like you might relapse, focus on your good experiences. Think about a time you made someone laugh.	Text your supporters & remind them of the big day. Make sure they have your back. We do! Text back CRAVE, MOOD, or SLIP for more support anytime.
Day 1	When you feel threatened by a craving to smoke, focus on your strengths. Think of a time you worked hard on something you care about.	You have good reasons for quitting. Say them out loud daily to help keep you on track, especially when you are feeling low.
Day 3	When you feel anxious about quitting smoking, focus on your values! Think of a time you showed compassion for another person, even if it was hard.	Stay away from people/places that make you think of smoking. You will find it easier to cope that way (and you will avoid secondhand smoke).
Day 12	Quitting is hard! When you feel a craving, think of a time you learned from a mistake.	Congratulations! Being smokefree means no longer cheating the things you love for something that doesn't love you back.
Day 24	When you feel threatened by a craving to smoke, focus on something important to you. Think of a time you helped a friend, even if you felt busy.	Strong healthy bones are another benefit of quitting. Quitting smoking reduces your risk of bone fractures now & later in life. Text STOP to end.

Measures

We assessed the number of days users remained enrolled following their quit date. Users who did not disenroll were assigned a value of 42.

Point prevalence cessation was assessed on users' quit date and weekly thereafter until day 42 with minor variations on, "Are you still smoke free? Reply: YES or NO." The qualitative responses from texts were recoded into quantitative values and uninterpretable responses were coded as missing.

Smoking frequency at enrollment (everyday, most days, some days, less than that) was collapsed into everyday versus other responses.

Overview of Analyses

We conducted analyses on: (1) those meeting eligibility criteria (initiators, *n*=1261), (2) those remaining enrolled throughout the 42-day intervention (completers, *n*=687), and (3) those reporting smoking status at 6 weeks (responders, *n*=81) (see Tables 2 and 3). These *a priori* criteria ensured that users could receive the baseline affirmation the night before their quit date, and the same criteria were applied across all conditions. Four outcomes were assessed: days enrolled, completion of intervention (dichotomous), smoking status at day 7 (1 week), and smoking status at day 42 (6 weeks). The former two outcomes were only assessed among initiators, as all completers and responders remained enrolled throughout the 42-day intervention. Among initiators and completers, nonresponse to smoking status was recoded as smoking (even if users disenrolled). SPSSv.21 was used to run *t*-tests and chi-square analyses testing for differences in the dependent variables as a function of condition.

Table 2. Attrition and response rates as a function of study condition.

	Affirmation *n*	Control *n*	Total *n*	Percentage of treatment initiators
Met eligibility criteria for analyses (treatment initiators)	650	611	1261	--
Remained enrolled through 42-day intervention period (treatment completers)	363	324	687	54.5
Responded to 42-day smoking cessation item (treatment responders)	40	41	81	6.4

Table 3. Reasons for ineligibility for analyses as a function of study condition.

	Affirmation	Control	Total
	n	*n*	*n*
Total number of users that were not eligible	856	942	1798
Under 18	0	13	13
Did not set a valid quit date (ie, did not set a quit date or set date for 3014)	37	62	99
Did not set a quit date at least one day after the day of enrollment and thus may have already tried to quit before receiving any affirmations[a]	613	669	1282
Did not remain enrolled in the study through selected quit date	172	183	355
Set quit date too far into the future	53	50	103

Note: Some users were ineligible for more than one reason

[a]Self-affirmation has been shown to be ineffective when introduced after defensive responses to a threat [19]; thus, individuals who did not have the opportunity to affirm prior to or at the time of trying to quit were ineligible.

Results

Among initiators, 35.8% (452 of 1261) were male and mean age was 35.5 years (SD=11.9, range=19-79). Most users (91.75%; 1157 of 1261) smoked daily. Among initiators, there were no significant differences in gender, age, or baseline smoking frequency across conditions (all *P*s>.22). Completers (t (1231)=−4.22, P<.001) and responders (t (1231)=−2.49, P=.010) were on average older than non-completers and non-responders, respectively, but did not differ in gender or baseline smoking frequency.

Among initiators, self-affirmation did not significantly improve any of the following: (1) intervention completion (54.6% overall; control: 324 of 611; affirmation: 363 of 650; $\chi^2(1)=1.01$, P=.315), (2) days enrolled (control: M=26.8 days; SD=17.5; affirmation: M=27.4 days; SD=17.7; t (1259)=−0.59; P=.553), or (3) 6-week smoking status (6% had quit overall; control: 32 of 611; affirmation: 39 of 650; $\chi^2(1)=0.35$; P=.557). Initiators who received affirmations were somewhat *less* likely to report cessation (9%, 61 of 650) at the 1-week follow-up than those who did not receive affirmations (12%, 75 of 611; $\chi^2(1)=2.73$, P=.098), although this was not statistically significant. Among completers, there were no significant effects of affirmation on cessation (1-week follow-up: 14% had quit overall, 49 of 324 control, 44 of 363 affirmation; 6-week follow-up: 10% had quit overall, 32 of 324 control, 39 of 363 affirmation, *P*s>.25).

Importantly, among the 81 responders, those who received affirmations were more likely to report cessation at the 6–week follow-up (98%, 39 of 40) than those who did not receive affirmations (78%, 32 of 41, $\chi^2(1)=7.08$, P=.008). There were no significant effects among responders for cessation at the 1-week follow-up (P=.57).

Of note, analyses including users who set quit dates 1) on the day of enrollment and 2) before or on the day of enrollment (testing whether any potential benefits extended to a sample of respondents that may have already attempted quitting) revealed no significant effects, consistent with evidence that self-affirmation is most effective before people can exhibit defensive responses to threat [19].

Discussion

This proof-of-concept study provides preliminary evidence that self-affirmation can be integrated into existing text-based cessation programs, as affirmations did not lead to adverse effects (ie, less engagement or lower rates of cessation). Among those who reported smoking status at the end of the intervention period (6.4% of eligible respondents), affirmations facilitated cessation. However, when using an intent-to-treat approach with all eligible users, self-affirmation did not improve outcomes. Although effects demonstrated in this pilot study were modest, incorporating self-affirmations into the program was nevertheless simple and did not increase user burden - suggesting that even a small observed benefit is likely to be cost-effective.

Affirmations *interspersed* into an mHealth intervention allow users multiple opportunities to engage with the content and may promote cessation, at least among individuals who remain engaged with the program. Most users did not complete the baseline affirmation questionnaire. Users may have perceived the questionnaire as irrelevant. Future research might integrate an affirmation questionnaire into the registration process and clarify its relevance to users. Taken as a whole, these results suggest that the effect of self-affirmations within “low-touch” mHealth interventions may be most useful in specific short-term therapeutic windows. More research is necessary to determine appropriate dosing and timing of affirmation messages, and to understand the potential usefulness of self-affirmation messages on clinically relevant behaviors (eg, retention, engagement, and behavior change).

Although the potential generalizability of user data from a population-mHealth cessation program is a strength, these data also had limitations. Data were collected within an intervention, rather than controlled research protocol conditions, and thus were limited by the parameters of the clinical service. In addition, it is typical to incentivize participation in research settings, and the lack of incentives undoubtedly contributed to low response rates. Response rates may have increased if contact was made beyond that provided by the clinical service. Last, the cessation measures in the protocol were less optimal than

smoking assessments of the last 7 days, and were not confirmed biologically.

We integrated an evidence-based approach (self-affirmation) into a real-world intervention delivered at the population level, providing a "proof-of-concept" that brief, low-touch interventions may be integrated into a text messaging program with potential benefits, minimal disruption, and little cost. However, many questions remain regarding how self-affirmation and similar approaches can promote engagement in population interventions.

Conflicts of Interest

None declared.

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Original Paper

Stepwise Development of a Text Messaging-Based Bullying Prevention Program for Middle School Students (BullyDown)

Michele L Ybarra[1], PhD; Tonya L Prescott[1], BA; Dorothy L Espelage[2], PhD

[1]Center for Innovative Public Health Research, San Clemente, CA, United States

[2]College of Education, University of Illinois at Urbana-Champaign, Champaign, IL, United States

Corresponding Author:
Michele L Ybarra, PhD
Center for Innovative Public Health Research
555 N El Camino Real A347
San Clemente, CA, 92672
United States
Phone: 1 8773026858
Fax: 1 8773026858
Email: Michele@InnovativePublicHealth.org

Abstract

Background: Bullying is a significant public health issue among middle school-aged youth. Current prevention programs have only a moderate impact. Cell phone text messaging technology (mHealth) can potentially overcome existing challenges, particularly those that are structural (e.g., limited time that teachers can devote to non-educational topics). To date, the description of the development of empirically-based mHealth-delivered bullying prevention programs are lacking in the literature.

Objective: To describe the development of BullyDown, a text messaging-based bullying prevention program for middle school students, guided by the Social-Emotional Learning model.

Methods: We implemented five activities over a 12-month period: (1) national focus groups (n=37 youth) to gather acceptability of program components; (2) development of content; (3) a national Content Advisory Team (n=9 youth) to confirm content tone; and (4) an internal team test of software functionality followed by a beta test (n=22 youth) to confirm the enrollment protocol and the feasibility and acceptability of the program.

Results: Recruitment experiences suggested that Facebook advertising was less efficient than using a recruitment firm to recruit youth nationally, and recruiting within schools for the pilot test was feasible. Feedback from the Content Advisory Team suggests a preference for 2-4 brief text messages per day. Beta test findings suggest that BullyDown is both feasible and acceptable: 100% of youth completed the follow-up survey, 86% of whom liked the program.

Conclusions: Text messaging appears to be a feasible and acceptable delivery method for bullying prevention programming delivered to middle school students.

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KEYWORDS

bullying; mhealth; text messaging; youth; prevention

Introduction

Background

Bullying is a significant adolescent health issue: depending on the type of bullying, an estimated 9% to 38% of middle school students bully their peers sometimes or more often each semester [1]. Defined as intentional peer aggression that occurs repetitively, over time, between at least two people for whom differential power exists [2], bullying is associated with negative psychosocial correlates, including externalizing problems (eg, alcohol use) for bullies and internalizing behaviors (eg, depressive symptomatology) [3-5], and suicidal ideation and attempts for victims [5,6]. Emerging research suggests that bullying also has a negative physiological impact: victims have greater changes in C-reactive protein as they age into adulthood [7]. Research also suggests dysregulation of the hypothalamic-pituitary-adrenal axis among adults who were victims of bullying, resulting in memory deficits [8]. Recent work further notes shorter telomeres, which implicates a shorter life expectancy, among those exposed to violence (eg, bullying

victimization) as children compared with nonexposed youth [9].

The Current State of Bullying Prevention Programs

Existing bullying prevention programs seem to be having a modest impact. [10-16]. Existing approaches, which rely on teachers to deliver proscriptive content, may cause youth to dismiss the messages as a way of rejecting authority and exerting control over their social selves [16]. Programs that are able to remove the teacher from the content delivery may be able to overcome this challenge [17].

The Potential for Technology to Affect Behavior Change

Many are exploring the potential for digital technology to enhance the educational experience and to promote prosocial behaviors [18,19]. The wide adoption of cell phones provides novel opportunities to "go where youth are." Indeed, 88% of 12- to 17-year-old youth have access to a cell phone. Ninety percent of these youth use text messaging (short message service, SMS) interventions [20], which is the preferred mode of communication between peers [21]. Furthermore, text messaging is cost-effective: compared with the high personnel and infrastructure costs of in-person interventions, text messaging-based programs (ie, mHealth) are scalable and cost less than US$.02 per message to send and receive. Moreover, emerging evidence supports the efficacy of these programs [22-26].

The Theory of Social-Emotional-Learning–Based Bullying Prevention Programs

Research suggests that effective behavior change programs are guided by strong theoretical models[27]. Social-Emotional-Learning (SEL)-based programs involve "the systematic development of a core set of social and emotional skills that help children more effectively handle life challenges and thrive in both their learning and their social environments" [28]. The model has emerged from influences across different movements that focused on resiliency and teaching social and emotional competencies to children and adolescents [29]. SEL is based on many well-established theories, including theories of emotional intelligence, social and emotional competence promotion, social developmental model, social information processing, and self-management [30]. It also integrates important aspects of several other behavior change models, including the health belief model, the theory of reasoned action, problem behavior theory, and social-cognitive theory [27,31].

SEL-based programs use social skills instruction to address behavior, discipline, safety, and academics in order to help youth become more self-aware, manage their emotions, build social skills (eg, empathy, perspective-taking, respect for diversity), build friendship skills, and decrease engagement in delinquent behavior [32-34]. SEL-based bullying prevention programs [34,35] target risk and protective factors that have consistently been associated with bullying and victimization in cross-sectional and longitudinal studies [36-43]. For example, empathy has been reliably found to be negatively associated with aggression and positively associated with prosocial skills [44-46]. The inverse correlation between aggression and empathy was found to be stronger in studies that focused on the emotional component of empathy than in studies in which cognitive empathy was measured [47]. Endresen and Olweus [47] conducted a study that specifically explored the association between empathy and bullying and brought attention to attitudes toward bullying, which have demonstrated positive correlations with bullying behavior [48]. Anger and hostility routinely emerge as important correlates of bullying. In several studies of bullying behavior, anger was the strongest predictor of bullying both cross-sectionally and longitudinally [48,49]. Impulsivity also plays an important role in bullying perpetration and victimization. In a prospective study of factors that predicted bullying over a 4-month period, Espelage et al [50] found a significant association between impulsivity and bullying behavior among a sample of 214 6th grade students. In addition, bullying prevention efforts have increasingly focused on the importance of bystander intervention, with significant results [37,51].

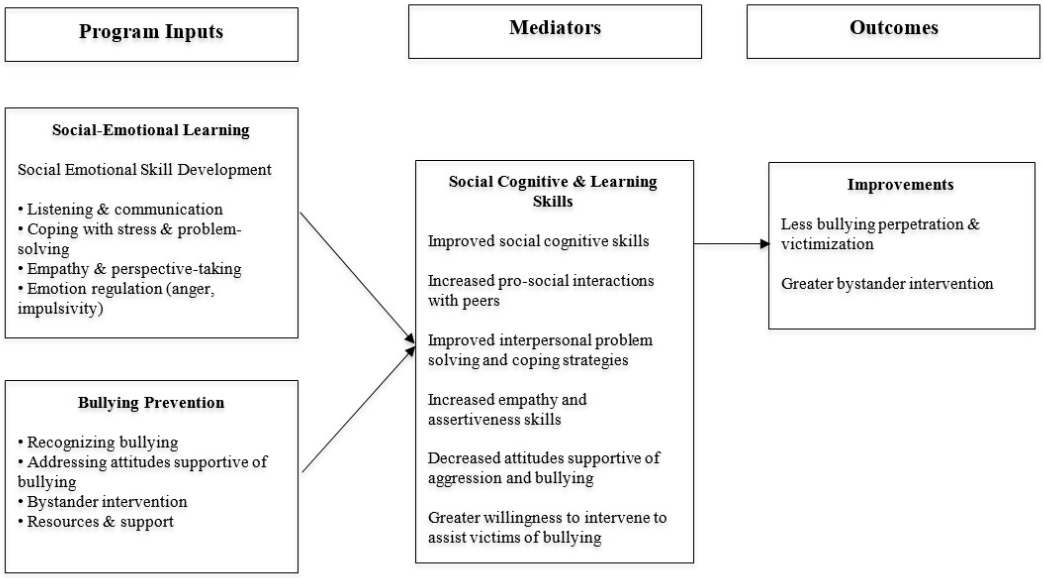
A Description of BullyDown, a mHealth Bullying Prevention Program

SEL-based programs have reported positive results in terms of reducing bullying and other disruptive behaviors in middle school [34,52,53]. As such, we used the SEL model to guide the development of BullyDown, a mHealth bullying prevention program designed for middle school students (Figure 1).

According to the SEL model, interactivity increases participant engagement, and new behaviors need to be practiced to be integrated into one's behavioral script. BullyDown therefore includes several features aimed at engaging youth, while also encouraging them to practice the skills discussed in the content. Principal among these is the "Text Buddy" feature, which pairs intervention participants as "buddies," allowing them to discuss what they learn through the program with each other. Text Buddy has been used successfully in other text messaging–based programs and is associated with behavior change [54-56]. As such, we posit that the Text Buddies feature will provide an opportunity for youth to process the program information and to practice their new skills in a safe environment. To further integrate interactivity and also ensure that youth understand the program information, youth are given the opportunity to "level up" (ie, move to the next level) at the end of each week by answering a quiz question correctly.

A third interactive feature tested for acceptability is Happy Genie, which sends intervention participants on-demand messages that provide positive encouragement. This type of feature is specific to the target audience and the topic, but is based upon other behavior change programs that have also used on-demand features [54-56].

Figure 1. Social-Emotional Learning logic model.



Current Paper

Similar to iterative methods used in other mHealth programming [57,58], Ybarra and colleagues [56,59,60] have described a stepwise approach to developing and testing health behavior change content delivered via text messaging. Here, we describe the procedures and experiences encountered while developing BullyDown. Findings can inform the future design of similar programs for middle school youth, as well as those aimed at reducing bullying and other aggressive behaviors.

Methods

The Chesapeake institutional review board reviewed and approved the research protocol. We sequentially implemented five activities: (1) online focus groups (FGs), (2) ongoing content development, (3) a Content Advisory Team (CAT), and (4) an internal team test, followed by (5) a beta test. We drafted content after conducting the FGs and continued refining content during the subsequent research activities. Research materials described herein are available via the Internet [61].

The development work spanned approximately 1 year: March 2014 to May 2015. For all research activities, study eligibility criteria matched those of the intended users of the intervention. Participants were enrolled in 7th or 8th grade (of exception, 6th graders took part in the FGs), owned a cell phone, were enrolled in an unlimited text messaging plan, intended to keep the same phone number for the next 6 months, had parental permission, and provided informed assent.

Focus Groups Methods

The FGs aimed to: better understand how young people experience bullying and their prior exposure to bullying prevention programs in school, to obtain the "voice" of the target population, and to query process issues. To gather feedback from a diverse group of youth nationally, our initial recruitment strategy relied on Facebook advertising targeted to US youth aged 13- to 14-years old (Figure 2).

Upon yielding a low response rate to the Facebook advertisements, we made subsequent changes to the recruitment strategy: increasing the Facebook ad budget from US$50 to US$100 per day, reducing the number of items on the Web-based screener to lower the completion time, and adding the company logo and link to the company website in the screener to increase the website legitimacy. We also contacted partner youth organizations who agreed to advertise for the research activity. When these attempts did not noticeably increase the number of eligible screeners, we contracted a research recruitment firm.

The research team developed a script of questions to guide the FG discussions. Example questions included:

When you think of the word "bullying," what do you think of? How (if at all) is this different from what you think of when you think about "aggression?" What about being angry? Or getting into fights with friends?

Has someone asked you to think about what it might feel like to be bullied? What are things that you do that help you understand how others might be feeling? Like how it might feel to be bullied or to bully someone?

Additionally, the FGs queried process issues, including the preferred number and timing of daily text messages and feedback on possible intervention names.

Two FGs of 20 participants each were conducted. The script was written to span 3 days of questions. We posited that youths' experiences and ability to articulate them would vary by grade level. As such, this was our stratification variable: FG1 was conducted with 6th and 7th graders, and FG2 with 7th and 8th

graders. Participants logged into the bulletin board–style FG discussion on a password-protected site two to three times each day when and where it was convenient for them. Because of its asynchronous format, participants from across a wide geographic area could be included. Participants received a US$50 Amazon gift card as an incentive for complete participation during all 3 days.

Figure 2. Focus group Facebook advertisements (2a).

Figure 3. Focus group Facebook advertisements (2b).

Content Advisory Team (CAT) Methods

We next convened a CAT to review and gather feedback about the saliency and understandability of the program content. The CAT also explored the acceptability of the three proposed program features: (1) Text Buddy, (2) Happy Genie, and (3) level-up questions.

To gather feedback, participants, or parents of participants when only the parent email address was available, received a Word document of the draft program text messages. The instructions asked youth to review and comment on each message within each week's module (eg, Communication). Probes were included to help give direction about what they could consider when reading the proposed content (eg, Are you able to read it and understand it easily?). Instructions also emphasized that the messages were still being developed and also necessarily short given the character limit of text messages. However, during this stage, the proposed text messages were longer than 160 characters (e.g., 180 characters), as the aim was to first identify appropriate tone and content.

Next, participants took part in a 2-day online discussion to share feedback as a group. For each weekly topic, moderators asked youth to identify their favorite, least favorite, most helpful, and least helpful messages; any messages that felt too long or short; and what they learned from the module. Moderators also asked participants about the proposed program features and to suggest three of their own Happy Genie messages. Participants earned up to a US$50 amount in an Amazon gift card, US$30 for their individual review, and US$20 for their participation in the online discussion.

Beta Test Methods

Findings were integrated into the program content, including feedback about the level-up questions and Happy Genie features. For example, to combat the judgment that bullies are "bad" (and therefore, implicitly, neither you nor your friends could be bullies) that emerged during the formative work, the level-up question during week 5 was:

> *Good morning and welcome to Week 5! Let's get you to Level 4. True or false: Bullies are mean to others because they are bad people. Text me back your answer.*

Those who responded correctly received the following reinforcing message:

> *Bullies are mean for lots of reasons but that doesn't mean they are bad people. Maybe they just need help learning how to share their feelings. Hello, Level 4!*

Those who responded incorrectly received the following response:

> *Actually, bullies can be mean for lots of reasons. That doesn't mean they are bad people. They might just need some help learning how to share their feelings.*

Youth who answered incorrectly were given additional chances to answer a new question correctly before they were automatically moved on to the next level:

> *Let's try again. For Level 4: True or false: Young people who act "differently" are asking to be bullied.*

Correct responses received the following:

> *Right! We're all different. Kids who act or look differently are just being themselves. They want to have friends just like everyone else. Hello, Level 4!*

Incorrect responses resulted in this text:

> *We're all different. Teens who act or look differently are just being themselves. They want to have friends just like everyone else. Onward to Level 4!*

Following a successful internal team test that confirmed the program software performed as intended and that the content was readable on cell phone screens, we conducted a beta test to confirm the feasibility of the protocol and technology in a school setting. To facilitate resolution of technology problems if needed, the beta test was conducted with participants from a low-income middle school in Illinois. Research staff went to the school in early December 2014 to screen 7th and 8th grade students from four preselected classrooms. Staff issued parental permission forms to eligible students to return in 1 week. During subsequent visits, research staff picked up the signed permission forms and facilitated enrollment (ie, obtaining informed assent from the students, helping the students complete the baseline Web-based survey in the school computer room, and verifying the students' phones for compatibility with the software program).

Participants were randomized to either the 7.5-week intervention or control group at a 2:1 ratio. This maximized the amount of information gathered about the intervention, while also gathering sufficient data about the control group experience to determine its feasibility and acceptability. To avoid school hours, participants received one program message in the morning (7:15 AM) and the remainder of messages after school hours (between 4:00 and 9:00 PM). Intervention participants received three to six messages per day for a total of 214 messages, with an additional 15 to 29 messages from the level-up feature; were randomly assigned a Text Buddy; and had access to Happy Genie. Control participants received two messages weekly, one message encouraging thoughtful behavior (eg, A message from BullyDown: "Try doing one nice thing for someone today") and the other thanking them for their participation, for a total of 14 messages. Control group participants did not have access to the Text Buddy and Happy Genie components.

In addition to the Web-based baseline survey, all participants were asked to complete a brief survey about their program experience, conducted via text message, every other week. We also conducted a Web-based follow-up survey 1 month post-intervention: youth received a link to the survey and two subsequent reminders via text message to facilitate self-completion. Those who did not complete the follow-up survey on their own could choose to complete the survey at school with research staff.

Participants received a US$10 cash incentive for returning the parent permission form, irrespective of whether they received permission. Participants received a US$25 Amazon gift card

upon completion of the 1 month post-intervention follow-up survey.

Results

Demographic characteristics of participants in the FGs and CAT, which were enrolled nationally; and the beta test, which was fielded in Illinois, are shown in Table 1. Bullying was somewhat common. For example, 23% (5/24) of beta test participants reported bullying someone via text messaging in the past 30 days.

Focus Group Results

Recruitment and Enrollment

FG activities occurred between March and May 2014. Although the Facebook ads generated a high number of impressions (343,148) and unique clicks (2334) after 10 days of advertising, only 13 screeners were received. Of these, four were from eligible youth. Reasons for ineligibility included not owning a cell phone (7/13, 54%), not being enrolled in an unlimited text messaging plan (1/13, 8%), and being too young (1/13, 8%).

The recruitment firm identified 18 participants to take part in FG1 and 19 participants in FG2. Two participants from FG1 and one from FG2 assented and enrolled, but neither completed the FG nor provided a reason for their nonparticipation.

Process Issues

In total, the FG moderators posted 23 threads, each containing between one and five questions. As predicted, participant age was an important process variable: 6th grade youth had difficulty responding to questions. Homeschooled youth did as well.

For example, in response to familiarity with bullying prevention programming at school, a 12-year-old male said: “Im homeshooled so we don't have any of that.” (Note here, and throughout, that youth quotes are presented exactly as they were typed by participants.)

Participants overwhelmingly voted for the program name “BullyDown.” As one participant shared: “I like BullyDown.com the best. It states the purpose of the website and it's easy to remember!” (13-year-old female). Youth also expressed a preference for receiving two to four program text messages per day and felt that more would be too many.

Program Content

While some youth reported that their schools had not discussed bullying, most youth were able to articulate and also agreed with school definitions of bullying: “Our school considers any type of picking on or hurting someone's feelings bullying and I feel the same.” (12-year-old male). Overall, youth related to the definition of bullying as verbal, physical, and relational forms of aggression that can happen among friends and nonfriends:

> *Bullying comes in many forms. Physical, mental and cyber are all kinds of bullying. To me bullying is picking on or hurting someone you know can't defend themselves. A person bullies others to feel better or more important about themselves. Being aggressive towards another person is not the same as bullying. To me aggression is more about anger and the anger one feels towards another.* [13-year-old female]

Youth perceptions of victims varied, and in some cases, youth felt that some victims behaved in ways that contributed to their victimization. Youth also recognized that some students who are socially popular engage in bullying, making it more difficult to stand up to these bullies. Because emotion regulation is a core component of bullying prevention, we also asked FG participants about coping strategies they used when stressed or upset. Answers included: reading/writing, listening to music, counting, belly breathing, and talking to siblings and parents.

Integrating Focus Group Feedback into BullyDown

Based upon the SEL model, we drafted seven modules: (1) communication, (2) coping with stress and problem solving, (3) empathy, perspective-taking, and respect for diversity, (4) recognizing bullying, attitudes toward bullying, and attitudes supportive of aggression, (5) emotion regulation: anger, hostility, and impulsivity, (6) bystanders and intentions to intervene to help others, and (7) resources and support.

Table 1. Demographic characteristics of BullyDown participants by development activity.

Demographic characteristics	Focus groups (n=37) n (%)	CAT[a] (n=9) n (%)	Beta test[b] (n=22) n (%)
Sex			
Male	18 (48.7)	6 (66.7)	8 (36.4)
Female	19 (51.4)	3 (33.3)	14 (63.6)
Age[c]			
11 years	1 (2.7)	NA	NA
12 years	17 (46.0)	4 (44.4)	10 (45.5)
13 years	16 (43.2)	4 (44.4)	8 (36.4)
14 years	3 (8.1)	1 (11.1)	4 (18.2)
Race/ethnicity[d]			
Caucasian	18 (48.7)	6 (66.7)	10 (45.5)
Black/African American	10 (27.0)	1 (11.1)	7 (31.8)
Asian	1 (2.7)	0 (0.0)	0 (0.0)
Mixed racial background	1 (2.7)	0 (0.0)	4 (18.2)
Native American or Alaskan Native	0 (0.0)	1 (11.1)	0 (0.0)
Hispanic	7 (18.9)	1 (11.1)	4 (18.2)
Do not want to answer	0 (0.0)	0 (0.0)	1 (4.56)
Grade[c]			
6th grade	12 (32.4)	NA	NA
7th grade	14 (37.8)	4 (44.4)	11 (50.0)
8th grade	11 (29.7)	5 (55.6)	11 (50.0)
Region			
Northeast	9 (24.3)	2 (22.2)	0 (0.0)
South	12 (32.4)	3 (33.3)	0 (0.0)
Midwest	8 (21.6)	2 (22.2)	22 (100.0)
West	8 (21.6)	2 (22.2)	0 (0.0)
Type of residence			
Urban	12 (32.4)	3 (33.3)	Not asked
Suburban	15 (40.5)	3 (33.3)	Not asked
Rural	10 (27.0)	3 (33.3)	Not asked
Been bullied[e]	10 (27.0)	6 (66.7)	14 (63.6)
Bullied someone[e]	5 (13.5)	2 (22.2)	5 (22.7)

[a]Content Advisory Team.

[b]Beta test participants were enrolled from a partner school in Illinois, as such all participants are from the Midwest region.

[c]Grade eligibility criterion was modified prior to the CAT to include grades 7 and 8 only.

[d]Hispanic ethnicity was queried as part of race for the focus groups and CAT, and as a separate identity in the beta test. As such, race/ethnicity sums to more than 22 for the latter activity.

[e]For the focus groups and CAT, youth were asked if they had ever bullied and if they had ever been bullied. In the beta test, a more complex series of questions were asked, including different ways in which youth could be bullied, the mode through which they could be bullied (eg, in-person, via the Internet), and the place that they could be bullied (eg, at school, on the way to and from school). The timeframe was limited to the past 30 days.

Table 2. Example BullyDown program messages by SEL component.

SEL Component	BullyDown program text message
Social	
Communication	Passive communication is when you don't really share an opinion: "I don't care;" "Whatever you want is fine;" and things like that. *(Week 1)*
Communication	It is also passive if you don't say anything. If someone teases you and you don't say anything, people may think you are ok with it or that it doesn't upset you. *(Week 1)*
Problem-solving	Step 1 in problem-solving is figuring out what the problem is. While this may sound easy, sometimes it can be harder than we think. *(Week 2)*
Respect for diversity	We're all different. Teens who act or look differently are just being themselves. They want to have friends just like everyone else. *(Week 5)*
Recognizing bullying	It can be a fine line between bullying and messing around. So how do you know where the line is? *(Week 4)*
Recognizing bullying	One teen said that it is no longer drama, but becomes bullying when the other person doesn't fight back - or they fight back but it doesn't work. *(Week 4)*
Attitudes supportive of bullying and aggression	Peer pressure is hard: maybe your friends dare you; or you think your friends will like you better; or your friends are teasing someone and you join in. *(Week 4)*
Bystanders and intentions to intervene	Good news! You don't have to do it alone. Let's talk about ways you can help kids who are in trouble. *(Week 7)*
Emotional	
Coping with stress	Let's talk more about what to do when you're down. Ask for help. Staying quiet doesn't make you stronger, often times it just makes you feel alone. *(Week 6)*
Empathy and perspective taking	It can be easy to make bad decisions when we're angry. This is really true if we don't try to understand what we're feeling and why. *(Week 4)*
Emotion regulation: anger, hostility	It's okay to get angry - we all get angry sometimes. It's what you do with that anger that is good or bad. *(Week 4)*
Emotion regulation: impulsivity	Listening to music, writing about it, or talking to someone can help. Even just sleeping on it can help you see that it is not such a big deal the next day. *(Week 4)*

We incorporated quotes, as well as personal experiences shared by youth, from the FGs into program messages. For example, youth responses included:

> *Bullying is something done to someone weaker then you that you know cant defend themselves. When you go behind the other persons back it usally means your scared to say it to there face.* [14-year-old male]

> *I saw a boy making fun of a handicapped student right in front of a teacher and they did not say anything, so I did and then they stopped it and the boy who was bullying was sent to the office.* [13-year-old female]

These became adapted into the respective program messages:

Bullying can even be spreading a rumor about someone (true or not). It can happen face-to-face or behind your back. It can be online or through text messaging.

Another teen said: A boy was making fun of a handicapped teen in front of a teacher, but she didn't say anything. So I did. The boy was sent to the office.

In response to a question about how bullying might make a person feel, a participant shared:

> *it makes you feel badly about yourself and that feeling lasts for a long time. It doesn't go away quickly, even if others try to tell you it's not true. Deep inside you feel like it is true what they are saying. It stays with you and keeps coming back and being in your mind.* [12-year-old female]

This was translated into the following program message:

A girl who was bullied told me: It makes you feel badly about yourself and that feeling lasts for a long time. It doesn't go away quickly……even if others try to tell you it is not true. Deep inside you feel like what they're saying is true. It stays with you and keeps coming back into your mind.

Content Advisory Team Results

Recruitment and Retention

We conducted the CAT between August and September 2014. Given the success using a recruitment firm during the FGs, we determined this strategy to be the most efficient for subsequent research activities. We excluded 6th graders and homeschooled youth in these subsequent activities because of their difficulty responding to questions during the FGs. The recruitment firm recruited 12 youth for the CAT (Table 1). Fifty percent (6/12) of participants completed both the individual text message review and the online discussion. Twenty-five percent (3/12) of participants completed only the individual review. Of these three nonparticipants, one parent withdrew their child from the study due to illness and lack of time to complete the CAT. Another parent requested a Web-based version of the survey,

which was provided although feedback was not received. The reason for the third youth's nonparticipation is unknown.

Engagement with the CAT was low in part because of participants' confusion about the protocol. Both the recruitment firm and the research staff received multiple requests from parents for clarification about the process. This confusion seemed to persist even after research staff explained the process to parents over the phone. Following up with participants and/or their parents was also difficult because messages from research staff often went unanswered. In many cases, the recruitment firm needed to contact parents and/or participants on behalf of research staff to resolve the issue. Response rates may also have been low because the CAT field period overlapped with the start of a new school year. After yielding little feedback, we extended the 7-day deadline by a week. To help invigorate completion, research staff provided participants with examples of the type of feedback that would be informative to program development. Interestingly, two participants requested that the messages be made available via the Internet through Google Docs. One did not have access to Word, and the other requested it for anticipated convenience.

Atypical of our past experience with adolescents [62], parents of CAT participants were often the point-of-contact. This is perhaps because the recruitment firm identified youth through their parents. As a result, we often lacked contact information for the youth. To avoid this issue in the future, researchers should consider including a study eligibility criterion that requires youth contact information or partnering with a recruitment firm that allows the project staff to talk directly to both parent and child at the outset of the study. Researchers should also be mindful of major transition periods for the target audience (eg, the beginning of a school year) when identifying desired field dates.

Text Message Review

As shown in Table 3, youth feedback to each of the messages were generally positive (eg, "Great job describing it") and, in some cases, elicited personalized responses (eg, "I hate being accused of being bully"). Although some program messages received more negative feedback than others (eg, the message for recognizing bullying; emotion regulation: impulsivity; a quote from cartoon character BMO), at least one-half of the participants positively endorsed most messages. A participant also made a comment in the "emotion regulation: anger, hostility" section suggesting that some of the daily transitions between topics needed improvement.

Online Discussion

During the 2-day online group discussion, participants generally rated the program modules positively: between 80% (4/5) and 100% (5/5 or 4/4, depending on the number of youth who responded to the poll) of youth liked/strongly liked them. As an exception, 75% (3/4) of youth disliked the problem-solving module. Only one youth provided details on his negative reaction to the module:

> *I liked the how to deal with stress messages, the tips on what to do. The examples about starting rumors was nothing I would ever do, so did not like that.* [12-year-old male]

When asked about their overall impression of the program, many participants responded positively:

> *the program is perfect no changes needed.* [13-year-old male]

Less enthusiastic feedback was also received:

> *some of the messages were too long and boring and some of them were kinda confusing* [12-year-old female]
>
> *it was jumping from topic to topic.* [13-year-old female]

Four youth had negative reactions to the tone of some messages. For example, one youth shared:

> *[the messages] sounded like an adult trying to be 'cool' - the messages were too long and wordy and sounded like things my mom would say.* [12-year-old male]

When asked for further detail, youth specifically disliked the use of the phrase "rock star" in one of the messages. Although many participants liked the inclusion of quotes from other teens, one youth questioned the authenticity of the quotes (ie, emotion regulation: anger, hostility message; Table 3).

The level-up feature was well received, although it too was not immune to criticism. For example, some thought that while the feature was acceptable, the questions needed to be more challenging:

> *the questions to get to the next level were way too easy. the second try was even more easy. you should probably make it a little harder.* [12-year-old male]

Another participant thought that the questions felt like homework:

> *… I don't like having to 'earn' levels - it makes it more like a school assignment, not something that should be have to be done. why do you have to pass a level to move on? is there a prize or something to get through the levels. If I was doing this in real life and did not pass a level, I would just stop and not continue anymore.* [12-year-old male]

Regarding program features, participants were enthusiastic about Happy Genie:

> *This genie feature looks amazing this is just what is needed when their life feels like a bore and nothing is great about it. The feature that it sends them a positive quote is very nice indeed. Overall great feature really perked up my spirits with those quotes i am sure it will do just the same for the participants.* [13-year-old male]

This sentiment was echoed by a 12-year-old female:

> *I think this feature is great! It could be really helpful for a person whose having a bad day.*

Youth also suggested several name alternatives, including Forever Friend, Good Day Genie, and the Happy Doctor.

Table 3. Example per-message feedback from the Content Advisory Team.

Message type	Specific program message	Participant feedback[a]			
		12-year-old male	**13-year-old female**	**12-year-old male**	**12-year-old male**
Communication	Assertive communication is when you're clear about how you feel or what you want. Say someone is being mean to your friend. You could say: "I think the way you put him down was mean."	*Ok, good*	*I like the messages when they describe an example of the type of communication which is what is happening in this one*	*Great job describing it*	*Glad itg explains it – but is too wordy*
Recognizing bullying	A teen told me that it's no longer drama, but becomes bullying when the other person doesn't fight back - or she fights back but it doesn't work.	*good*	*I like this message because as you know, I like hearing from other teens*	*Way to use examples*	*Not sure if that is right*
Attitudes supportive of bullying and aggression	Remember: There are lots of ways to make friends without bullying. If your friends are pressuring you to be mean to others, maybe they're not such good friends.	*Good message*	*I like this message because I think that so many people get caught up in who they want to be their friend, when they aren't such good friends*	*Put a but before maybe*	*I stopped being friends with someone because I was tired of them bullying people all the time*
Coping with stress	There are lots of ways to deal with stress. You could go on a long walk, play basketball, read a book, go for a run or a bike ride, or even write a poem!	*Sounds good*	*I like this message because it has a variety of things to do when your stressed*	*Add "anything that helps*	*Good examples – but who would write a poem? Ick!*
Empathy and perspective taking	Maybe someone has called you a bully but you didn't know you hurt the person. This can be frustrating. Take a moment to think about why the other person may have felt bullied.	*yes*	*I like this message because I feel like if someone is accused of bullying, they seem to forget*	*I hate being accused of being bully*	*I have never been told I bullied someone*
Emotion regulation: anger, hostility	Imagine you're in a fight with your friend. To deal with it, you could: stop talking to her. Shove her to show her you're mad. Make up a rumor about her. Or, tell her how you feel.	*good*	*I like this message but it is kind of a weird ending message for the day*	*They know what the right answer, but that would be awkward to say*	*Sometimes I would not talk to her but I would never shove her or start a rumor – that's mean!*
Emotion regulation: anger, hostility	A teen told me: "I try to think about the situation before acting. If I can remember to do that, it works. But when I'm angry I usually forget those things."	*ok*	*I like this message because I like hearing words from other teens*	*Way to put in a quote*	*No teen talks like that*
Emotion regulation: impulsivity	You don't want to say something you'll regret. Trying to get even with a bully continues the cycle. And it might put you at risk for something unsafe to happen.	*yes*	*I like this message because it is very clear and is easy to understand*	*Yea, the bully could bet you up*	*Not needed – bad message*
Quote	Great advice: When bad things happen, I know you want to believe they are a joke, but sometimes, life is scary and dark. That is why we must find the light." - BMO)	*agree*	*I'm kind of confused with this and I'm not quite sure if this is supposed to be a quote or not*	*What is bmo?*	*Find the light? Not sure what this means*
		13-year-old male	**13-year-old female**	**12-year-old female**	**13-year-old male**
Communication	Assertive communication is when you're clear about how you feel or what you want. Say someone is being mean to your friend. You could say: "I think the way you put him down was mean."	*Great example on this type of communication.*	*i dont really use assertive communication*	*Needs a better example. Definition is clear*	*Bad*

Message type	Specific program message	Participant feedback[a]			
Recognizing bullying	A teen told me that it's no longer drama, but becomes bullying when the other person doesn't fight back - or she fights back but it doesn't work.	*I don't think this statement is true because I believe being able to identify it isn't so simple*	*i dont agree*		*Ok*
Attitudes supportive of bullying and aggression	Remember: There are lots of ways to make friends without bullying. If your friends are pressuring you to be mean to others, maybe they're not such good friends.	*Another good comment and a way to point out that maybe someone who is pressuring you isn't good to be around.*	*i hate it when my friend wants me to be mean. i hate being mean. i get a bad feeling inside*		*Ok*
Coping with stress	There are lots of ways to deal with stress. You could go on a long walk, play basketball, read a book, go for a run or a bike ride, or even write a poem!	*Great useful advice on how to deal with stress*	*i go outside*		*Ok*
Empathy and perspective taking	Maybe someone has called you a bully but you didn't know you hurt the person. This can be frustrating. Take a moment to think about why the other person may have felt bullied.	*I good suggestion and way to get someone to stop and think about their actions.*	*okay*		*Good*
Emotion regulation: anger, hostility	Imagine you're in a fight with your friend. To deal with it, you could: stop talking to her. Shove her to show her you're mad. Make up a rumor about her. Or, tell her how you feel.	*This a great example for this type of situation.*	*id just tell her how i feel i guess*	*Make it a little more clear but good options*	*Good*
Emotion regulation: anger, hostility	A teen told me: "I try to think about the situation before acting. If I can remember to do that, it works. But when I'm angry I usually forget those things."	*I like this comment I think it's very true*	*i think sometimes before i act*		*Ok*
Emotion regulation: impulsivity	You don't want to say something you'll regret. Trying to get even with a bully continues the cycle. And it might put you at risk for something unsafe to happen.	*A good comment and way to look at it*	*getting even makes me feel bad even though they've hurt me*		*Feel like im being talked down to*
Quote	Great advice: When bad things happen, I know you want to believe they are a joke, but sometimes, life is scary and dark. That is why we must find the light." - BMO)	*Very helpful advice and positive.*	*nice quote*		*Ok*

[a]To maintain participant voice, quotes are verbatim. As such, grammar and spelling errors exist.

Integrating Content Advisory Team Feedback Into BullyDown

Overlapping feedback provided by two or more youth were integrated into the program content where possible. For example, we deleted the word "rock star" and messages deemed particularly confusing (eg, the quote from BMO). We also modified the tone of messages to sound less motherly or adult-like. The message:

You can tell your friend how you feel. It might be hard. And it might not go well. But if you're in a healthy friendship and you use assertive communication, it could go great!

Subsequently became:

Tell your friend how you feel. It might be hard, and it might not go well. But if you're in a healthy friendship, and you talk assertively, it might go great!

We also reviewed the messages scheduled for the beginning and end of each program day for their flow and transitions, based on youth feedback.

We chose not to make the level-up questions more challenging as this seemed likely to make the feature further simulate homework. The level-up protocol was already designed to automatically move nonresponsive participants to the next module if they did not respond to the questions after a certain period. We established a plan to closely monitor participant reactions to the level-up feature during the beta test for further indication of acceptability.

We deemed participants' positive review of Happy Genie as supportive of its acceptability. We renamed the feature "Forever Friend" based on the names suggested by participants and added inspirational messages (eg, A new day = a new beginning) and quotes from famous people (eg, "I've failed over and over again in my life. And that is why I succeed." – Michael Jordan).

Beta Test Results

Recruitment and Enrollment

Enrollment spanned 3 months and required research staff to visit the partnered middle school four times. Research staff screened 78 youth, 45% (35/78) of whom were eligible. Reasons for ineligibility included: not having a cell phone (21/78, 27%), not or uncertain if they were enrolled in an unlimited text messaging plan (9/78, 12%), and not planning to or uncertain if they would have the same phone number for at least 6 months (21/78, 27%), including the possibility that parents may take away phone privileges as a form of punishment.

Thirty-three eligible youth returned their permission forms, all of whom had parental permission to participate. Twenty-four eligible students provided written assent to participate, of which 22 completed the registration process and were randomized. Of the nine youth who had parental permission but did not enroll, three changed their mind, two moved, one was absent every time the research staff went to the school, and three had problems with phone access (eg, one shared the phone with a parent). Reasons for not completing the registration process included no longer being interested (n=1) and no longer having a cell phone (n=1). Participants were successfully randomized, resulting in 14 students assigned to BullyDown and eight to the control group (Table 1).

Process Issues

We conducted the beta test between December 2014 and May 2015. No concerns from the school administration or staff were expressed during the field period. Participants encountered some technology difficulties, however. The school's firewall initially blocked the project enrollment website, but school technology staff quickly resolved the issue. Additionally, many students forgot to bring their phones to verify its compatibility with the program software. These students completed the Web-based baseline survey and were instructed to complete enrollment at home by responding with the word "verify" to the text message verification. Those randomized to the intervention group received a link to the Text Buddy Code of Conduct to read and accept. Some students had trouble completing the tasks, requiring research staff to return to the school to assist them in person.

Thirty-six percent (8/22) of participants completed the Web-based follow-up survey on their own time, and 14 completed it at school. The primary reason for not completing the survey independently was forgetting to do it. One participant thought the survey link did not look legitimate and so was hesitant to click on the link.

Program Acceptability and Feasibility

During the program delivery period, 86% (12/14) of intervention participants sent at least one message to their Text Buddy (range, 2-52), and 29% (4/14) sent at least one message to Happy Genie (range, 1-8). Half of intervention participants (7/14) responded to all seven weekly level-up questions, and 21% (3/14) responded to two or fewer level-up questions.

Feedback from the biweekly brief survey (Table 4) suggested that many intervention participants thought the messages were interesting and fun, although some felt the messages were boring (eg, week 2 messages). Seventy-five percent (9/12) of intervention youth were able to provide an example of a message they found memorable (week 4), and 75% (9/12) of youth provided a specific example of something they liked about the program (week 6).

Table 4. Beta test intervention group participant biweekly qualitative feedback.

Week	Program Message	Feedback per participant[a,b]			
		13-year-old male	**12-year-old male**	**13-year-old female**	**12-year-old female**
2	What do you think of the messages? Are they confusing? Boring? Interesting? Fun? Text me back what you think and why. The more details, the better.	*They are interesting and informative!*	*They have been helpful*	*Borin and fun, I already know half of the information you send me but I like the interactive texts*	*They are fun bc it tells me more information about the program*
	Is there anything about your experience in BullyDown that you'd like me to know at this point? Text your feedback or text “no.”	*I think there are too many texts per day.*	*Not right now no*	*No*	*U guys have told me most of the stuff I didn't know*
4	What one BullyDown text message sticks out in your mind, and why? This could be any message you've received since the start of the program.	*Being your loudest supporter because it shows that you should push yourself to do your best.*	*Believe you can and your halfway there.*	*All of the things to do when you are stressed..*	*To close ur eye when ur stressed*
	Is there anything about your experience in the program that you'd like me to know at this point? Text your feedback or text “no”.	*No*	*No*	*No.*	*No*
6	What is one thing that you really like about BullyDown and why? The more detailed you can be, the better.	*I like the daily advice and the inspirational messages.*	*I like all of the possible solutions. To the problems that kids have to deal with everyday. A Lot of. Kids don't kno how to handle situations*	*The one thing that I like is that it gives advice, it may be things that you already know it's something..*	*That I can learn more stuff about bullying and stuff like that I al so can ask questions about anything I need to know about bullying*
	And what is one thing that you really do not like about BullyDown or think that we need to make better, and why? Again, detail is helpful.	*Maybe not text as much through the day. Maybe just once in the morning and once at night.*	*Sometimes there are a lot of txts and it gets. Confusing*	*I think that BullyDown needs to be a place that people feel safe to explain how they feel and why they are feeling that way, but I honestly don't feel th at way. So to make it better you could let people talk with someone through text, instead of just giving advice.*	*I like everything about bully down*
	What else about your experience in the program would you like me to know at this point? Text your feedback or text “nothing”.	*Nothing*	*When I txt my bullydown friend. They don't reply*	*Nothing*	*Nothing*
8	How would you rate the number of messages that we send you each week? Too few, too many, or just right? Text me what you think.	*Too many.*	*Sometimes too many*	*Just right.*	*Just right*
	Is there anything about the program that you'd like me to know about your experience at this point? Text “no” or text your feedback.	*No*	*Having a bully buddy isn't a good idea. They don't reply to the text questions*	*No*	*No*
2	What do you think of the messages? Are they confusing? Boring? Interesting? Fun? Text me back what you think and why. The more details, the better.	*I am confused about what I should be texting to my text Buddy and when. I respond to your text when you ask a question but up until yesterday I hadnt texted my Buddy.*	*Interesting because I don't know what stuff you are going to text me.*	*Boring and interesting*	*Really idk its kinda confusing because when u asked me some of the question I got confused when I went to look for the answer and I got it wrong*

Week	Program Message	Feedback per participant[a,b]			
	Is there anything about your experience in BullyDown that you'd like me to know at this point? Text your feedback or text “no”.	*No*	*No*	*No*	*No not really*
4	What one BullyDown text message sticks out in your mind, and why? This could be any message you've received since the start of the program.	*When Im angry I usually go to my room and try to get something else on my mind. I end up later thinking about the situation and thinking it through.*	*The Forever Friend* [c] *texts. They cheer me up*	*The one about anger and the things I could do to prevent it. I liked that one because sometimes I get carried away and I get anger for no reason..*	*about calming your anger down why because it really helps when I am angry and when I am depressed about something*
	Is there anything about your experience in the program that you'd like me to know at this point? Text your feedback or text “no”.	*No*	*No.*	*No*	*No not really*
6	What is one thing that you really like about BullyDown and why? The more detailed you can be, the better.	*Ok*	*Forever friemd because it cheers me up*	*I like how y'all go in depth with every situation*	*ack and view what I have learned on here and what I already knew and if I was being a bully I would remember all the stuff I was taught*
	And what is one thing that you really do not like about BullyDown or think that we need to make better, and why? Again, detail is helpful.	*Sometimes the times of the texts are not convenient for a response since we are students that may be involved in other activities.*	*The texts I get back to back because I can't keep up*	*Maybe that y'all could slow down on the text messages*	*I like how they go step by step trying to prevent us from being and getting bullied I like that because if someone was gettin bullied I can either look b*
	What else about your experience in the program would you like me to know at this point? Text your feedback or text “nothing”.	*Ok*	*Nothing*	*Nothing*	*Nothing*
8	How would you rate the number of messages that we send you each week? Too few, too many, or just right? Text me what you think.	*Ok*	*Just right*	*Just right*	*Too many*
	Is there anything about the program that you'd like me to know about your experience at this point? Text “no” or text your feedback.	*No*	*No*	*No*	*No*
		12-year-old female	**13-year-old female**	**12-year-old female**	**13-year-old male**
2	What do you think of the messages? Are they confusing? Boring? Interesting? Fun? Text me back what you think and why. The more details, the better.	*Confusing Also I still havent talk to my buddy*	*Boring*		
	Is there anything about your experience in BullyDown that you'd like me to know at this point? Text your feedback or text “no”.				
4	What one BullyDown text message sticks out in your mind, and why? This could be any message you've received since the start of the program.	*Ok*		*The one about if my friend doesn't tell me she isn't coming to lunch*	

Week	Program Message	Feedback per participant[a,b]		
	Is there anything about your experience in the program that you'd like me to know at this point? Text your feedback or text “no”.	*Who is my buddy and how do I contact them*	*No*	
6	What is one thing that you really like about BullyDown and why? The more detailed you can be, the better.	*Yes*	*It. Gives you advice*	*I like Bullydown because it has really made me see how people can get bullied and how it can effect them and the different types of buling there is*
	And what is one thing that you really do not like about BullyDown or think that we need to make better, and why? Again, detail is helpful.	*Nothing*	*Make questions more deep*	*I really don't think that you men and women missed anything major*
	What else about your experience in the program would you like me to know at this point? Text your feedback or text “nothing”.	*Nonthing*	*Nothing*	
8	How would you rate the number of messages that we send you each week? Too few, too many, or just right? Text me what you think.			
	Is there anything about the program that you'd like me to know about your experience at this point? Text “no” or text your feedback.			

[a]To maintain participant voice, quotes are verbatim. As such, grammar and spelling errors exist.

[b]Blank spaces indicate a lack of response.

[c]“Forever Friend” refers to the Happy Genie feature.

Moreover, all participants said they would recommend the program to a friend when asked at the end of week 6 (Table 5). Opportunities for improvement were also noted: although 80% (8/10) of intervention participants agreed that reading the messages the same day they were received was easy (Table 5), five youth shared concerns about the message quantity or timing when asked at the end of week 6 about something they may not like about the program (Table 4).

Feedback from intervention participants suggested that they were enthusiastic about having a Text Buddy. This feature also drew at least one negative response each week, however (Table 4). Subsequent follow-up with youth revealed that their discomfort centered on being paired with someone from the same school and having to talk about bullying with a schoolmate: “…A Lot of kids in this area kno each other and don't want to talk about things like this.” (12-year-old male). Some youth also expressed frustration that their buddies were unresponsive to their messages; or felt discomfort about being paired with someone of the other sex or in a different grade.

As shown in Table 5, both the intervention and control group content appeared to be acceptable: more than four in five youth in each arm agreed that they liked the program. With 88% (7/8) of control participants saying that the program helped them not bully others in the future, this arm, although of lesser intensity than the intervention arm, appeared to blind participants to their arm assignment. In addition to high scores for understandability and salience of program content, the experience also seemed to be feasible: most youth disagreed or strongly disagreed that the program sent too many messages, and none of the beta test participants in either arm agreed that they stopped reading the messages by the end of the program.

Table 5. Acceptability and feasibility data from pilot test participants.

Youth responses	Control n (%)[a]	Intervention n (%)
Biweekly survey in field		
	(n=6)	(n=10)
How much are you liking BullyDown? (Week 2)	NA[b,c]	8 (80.0)
How easy or hard has it been to read your texts the *same* day we send them to you? (Week 4)	5 (83.3)	8 (80.0)
	(n=5)	(n=8)
How likely are you to recommend BullyDown to your friends? (Week 6)	3 (60.0)	8 (100.0)
One-month follow-up survey	(n=8)	(n=14)
Acceptability (Agree/Strongly Agree)		
I like the program	7 (87.5)	12 (85.7)
I learned things in BullyDown…		
That will help me not bully others in the future	7 (87.5)	14 (100.0)
That will help me not be bullied by others in the future	6 (75.0)	12 (85.7)
That will help me stop bullying when I see it happening to others	6 (75.0)	13 (92.9)
I do not think people like me should go through the BullyDown program (Disagree/Strongly Disagree)	7 (87.5)	10 (71.4)
BullyDown talked too much about… (disagree/strongly disagree)		
Feelings	7 (87.5)	8 (57.1)
Bullying	7 (87.5)	11 (78.6)
The text messages were easy to understand	6 (75.0)	12 (85.7)
BullyDown talked about things my friends and I experience in our lives	6 (75.0)	11 (78.6)
Feasibility (disagree/strongly disagree)		
BullyDown sent too many messages	7 (87.5)	10 (71.4)
I stopped reading the messages by the end of the BullyDown program	8 (100.0)	10 (71.4)
BullyDown got in the way of my daily schedule	8 (100.0)	10 (71.4)

[a]Percentages reflect those in the extreme categories: agree or strongly agree (4 or 5 on a 5-point Likert scale; 7-10 on a 10-point ordinal scale); disagree or strongly disagree (1 or 2 on a 5-point Likert scale; 1 or 2 on a 5-point ordinal scale).

[b]The control group inadvertently did not receive the Week 2 biweekly survey.

[c]not asked.

The enrollment process seemed to require in-person facilitation by research staff at a level that is at least commensurate with an in-person intervention. Both interesting and potentially problematic, 33% (11/33) of youth who were eligible and had parental permission lost interest in participating before enrollment. Given the small sample size, this may be an anomaly. Further investigation of this feasibility issue in a larger trial is needed before conclusions can be drawn. Also, some participants shared that they would have been more likely to respond to the follow-up survey if the link had been sent by email instead of text message. Future efforts should consider collecting multiple forms of contact (eg, Facebook, email address).

Despite CAT participants' expressed interest in the concept of Text Buddy, most beta test participants only sent one or two messages to their buddy. Based upon their feedback, future trials could ideally match Text Buddies who are attending different schools and, when possible, of the same sex and grade level. An interactive guide, either in-person or via the Internet, instructing how to use the feature could also be incorporated into the content. Additionally, only participants with expressed interest in the Text Buddy feature could be matched to reduce the likelihood of unresponsive buddies.

Several intervention youth expressed concern about the intensity and/or timing of the daily messages during the field period but not when it was assessed at 1-month follow-up. This feedback

most likely arose on days that had five or six messages, resulting in participants receiving four or five messages across a 4-hour window after school. To ameliorate this, the total number of messages per day in future iterations of the program will be limited to four where possible.

Consistent with feedback from some CAT participants who thought the level-up questions were too easy, one beta test participant thought that the questions should be more meaningful. Given the lack of negative feedback from other beta test participants about the level-up experience and the desire to avoid simulating homework however, more feedback from randomized controlled trial participants will be solicited before making significant changes.

Discussion

Principle Findings

Stepwise development of BullyDown over a 1-year period helped ensure the program was generally well received by middle school students. Findings reveal important insights about developing mHealth interventions for younger youth, particularly those focused on bullying prevention, including the preferred number of messages per day (ie, 2-4 messages), a desire for shorter messages, and the ideal age range (ie, 7th grade and older). In interventions aimed at older adolescents (e.g. 14- to 17-years old), others have noted a similar preference among participants for a low-intensity experience in interventions [63,64]; however, higher intensity programs (eg, 8-15 messages per day) have also received indications of acceptability [56]. The desired threshold seems likely to be affected not only by the age of the youth but also the topic in question. This variability in participants' acceptability of various program intensities highlights the importance of iteratively developing new mHealth program using ongoing feedback from the target population.

Also contrasting other mHealth adolescent recruitment efforts [65], Facebook was less efficient in nationally recruiting youth than was a more traditional recruitment method (ie, using a recruitment firm). Initial interest in the ads was commensurate with expectations for a successful campaign, but completion of the Web-based screener seemed to be an issue. Perhaps younger youth are more cautious when providing contact information to unknown people or organizations via the Internet, or perhaps the topic (ie, bullying prevention), when more fully explained, is of little interest to youth. However, the school administrator's enthusiasm for the beta test suggests that the program is acceptable and feasible for implementation in school-based samples. It also supports a hypothesis that the eventual program will need to be promoted to school administrators rather than youth directly.

Several additional differences between the experiences in the BullyDown beta test with the implementation of other text messaging–based health behavior change programs should be noted. For example, compared with high school-aged youth [56], middle school students' relationship with their phones seems to be less predictable: (1) they do not carry their phones everywhere – at least not to school and not necessarily outside of school, (2) they might not remember their phone number accurately, and (3) their access appears to be more tenuous – parents are more likely to restrict their cell phone use. Also, staff resources needed to enroll youth appear to be commensurate with in-person interventions. This means that cost savings in enrollment will not be realized. Once the intervention program messages begin however, most 7th and 8th graders are able to engage with the program on their own, suggesting that once engaged, a standalone technology intervention has promise. These differences highlight the heterogeneity of mHealth research: simply because a particular protocol works for one program and population does not mean the same protocol will work with other programs and populations.

Although control and intervention participants attended classes side by side, the control arm appears to have been blinded: they were equally likely as the intervention arm to say they liked the program, and a similar percent of youth said they learned valuable things about bullying during the program. This suggests that randomization at the individual-level may not pose a serious threat to contamination; however, results should be replicated in a larger sample size.

Limitations

Specific program recommendations that emerged from this work may not generalize to other health behavior change topics or youth populations. Although the national recruitment strategy is a strength, FG and CAT participants may not be representative of all youth given they were identified through a recruitment firm. Beta test participants were recruited from a disadvantaged public middle school in Illinois and may not be representative of students in other settings. More generally, youth who have a cell phone and are enrolled in an unlimited text messaging plan may be different from youth who do not meet these criteria. It seems unlikely however that youth who lack a cell phone or are not on an unlimited text messaging plan would opt into such a program if it was publicly available. Additionally, confirming that youth actually read the text messages is not possible beyond their self-report; therefore, actual exposure is unknown.

Conclusion

Increasingly, SEL programs are being implemented in schools across the United States to address a wide-range of problematic behaviors (eg, bullying, delinquency) and to promote academic success. However, the majority of these programs include curricula that range from 15 to 20 or more lessons, requiring significant instructional time and resources that some school districts may not be able to provide. BullyDown harnesses the benefits of text messaging, such as being able to go where youth are and communicating important information in consumable chunks, to offer a bullying prevention program that can be delivered outside of school and without the need for facilitator time or resources. While expensive in time and money, iterative intervention refinement increases the likelihood that the resulting intervention is salient to the target population while retaining its adherence to theory.

Given the positive feedback from beta test participants about the program content and the experience as well as the 100% (22/22) retention rate, the BullyDown mHealth bullying

prevention program appears to be both feasible and acceptable for implementation in a middle school setting with 7th and 8th grade youth. Our next step will be to test the intervention in a large randomized controlled trial to see if exposure is associated with reduction in bullying behavior.

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Conflicts of Interest

None declared.

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Abbreviations

CAT: content advisory team
FG: focus group
SEL: social-emotional-learning
SMS: short message service

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Original Paper

Development and Testing of an Automated 4-Day Text Messaging Guidance as an Aid for Improving Colonoscopy Preparation

Benjamin Michael Walter[1], Dr. med; Peter Klare[1], Dr med; Bruno Neu[1], PD Dr med; Roland M Schmid[1], Prof Dr med; Stefan von Delius[1], PD Dr med

II. Medizinische Klinik und Poliklinik, Klinikum rechts der Isar, TU München, München, Germany

Corresponding Author:
Benjamin Michael Walter, Dr. med
II. Medizinische Klinik und Poliklinik
Klinikum rechts der Isar
TU München
Ismaningerstr.22
81675
München,
Germany
Phone: 49 4140 2223
Fax: 49 4140 2451
Email: Benjamin.walter@lrz.tum.de

Abstract

Background: In gastroenterology a sufficient colon cleansing improves adenoma detection rate and prevents the need for preterm repeat colonoscopies due to invalid preparation. It has been shown that patient education is of major importance for improvement of colon cleansing.

Objective: Objective of this study was to assess the function of an automated text messaging (short message service, SMS)–supported colonoscopy preparation starting 4 days before colonoscopy appointment.

Methods: After preevaluation to assess mobile phone usage in the patient population for relevance of this approach, a Web-based, automated SMS text messaging system was developed, following which a single-center feasibility study at a tertiary care center was performed. Patients scheduled for outpatient colonoscopy were invited to participate. Patients enrolled in the study group received automated information about dietary recommendations and bowel cleansing during colonoscopy preparation. Data of outpatient colonoscopies with regular preparation procedure were used for pair matching and served as control. Primary end point was feasibility of SMS text messaging support in colonoscopy preparation assessed as stable and satisfactory function of the system. Secondary end points were quality of bowel preparation according to the Boston Bowel Preparation Scale (BBPS) and patient satisfaction with SMS text messaging–provided information assessed by a questionnaire.

Results: Web-based SMS text messaging–supported colonoscopy preparation was successful and feasible in 19 of 20 patients. Mean (standard error of the mean, SEM) total BBPS score was slightly higher in the SMS group than in the control group (7.3, SEM 0.3 vs 6.4, SEM 0.2) and for each colonic region (left, transverse, and right colon). Patient satisfaction regarding SMS text messaging–based information was high.

Conclusions: Using SMS for colonoscopy preparation with 4 days' guidance including dietary recommendation is a new approach to improve colonoscopy preparation. Quality of colonoscopy preparation was sufficient and patients were highly satisfied with the system during colonoscopy preparation.

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KEYWORDS

short message service; patient education; colonoscopy; colonoscopy preparation

Introduction

An optimal bowel preparation for colonoscopy is one of the most important cornerstones for gastroenterologists. A poor bowel preparation is associated with decreased adenoma detection, longer examination, and increased costs by virtue of the decreased interval to repeat examination [1-3]. Bowel preparation is inadequate in an estimated 15% to more than 20% of patients undergoing colonoscopy [2,4]. Misunderstanding dietary recommendations and cleansing instructions, as well as noncompliance, plays a major role in poor bowel preparation [4]. Information about diet and the preparation procedure is usually provided to patients before endoscopy after scheduling the colonoscopy appointment. Further education and continuous guidance of patients before colonoscopy has been shown to ensure quality of colonoscopy preparation and patient compliance [5]. In Germany, colon cancer prevention program starts at the age of 50 years, with a full insurance-covered outpatient colonoscopy starting at the age of 55 years. Participation rate in colon cancer prevention is low in Germany as it is in the rest of Europe. Colonoscopy preparation is especially reported to be unpleasant [1].

Over the last few years, there has been an enormous increase in the use of mobile phones in the overall population as well as among patients of all ages. Integration of such new media into colonoscopy preparation could help optimize the preparation procedure. We decided to use the well-established medium short message service (SMS), because SMS text messaging can be easily used for every type and age of mobile phone.

First, we performed a preevaluation to assess mobile phone usage in our patient population. A questionnaire was administered in order to analyze how many people already own and use mobile phones.

Second, an automated SMS text messaging system for colonoscopy preparation starting 4 days before colonoscopy was developed and tested in the following study.

The primary aim of the *PERICLES I* (*prospective evaluation for improvement of colonoscopy preparation procedure by software supported visualization*) study was to evaluate if a newly developed automated SMS text messaging reminder system starting 4 days before colonoscopy, containing dietary and behavioral recommendations, is feasible. Secondary end points were patient satisfaction with the system and the quality of bowel preparation.

Methods

To assess mobile phone usage in our patient population, we performed a preevaluation by administering a questionnaire.

Preevaluation of Mobile Phone Usage

For the analysis of percentage of patients who own and regularly use a mobile phone, a questionnaire study was initiated at our hospital. In total 349 patients were invited to participate. A total of 300 patients agreed to participate. Age, sex, and additional information about the type of mobile phone used—that is, mobile phone, smartphone (eg, iPhone, Samsung), or none—were collected and analyzed.

Text Messaging System Development

In cooperation with the company SmartPatient a fully automated, Web-based SMS text messaging reminder system containing important information on colonoscopy preparation was developed. It contains 15 messages (up to 160 characters each) that could be sent to a patient's mobile phone. For the content of the SMS text messages we decided to follow the general recommendations for outpatient colonoscopy, provided in a paper-based leaflet, used at our hospital starting 4 days before colonoscopy.

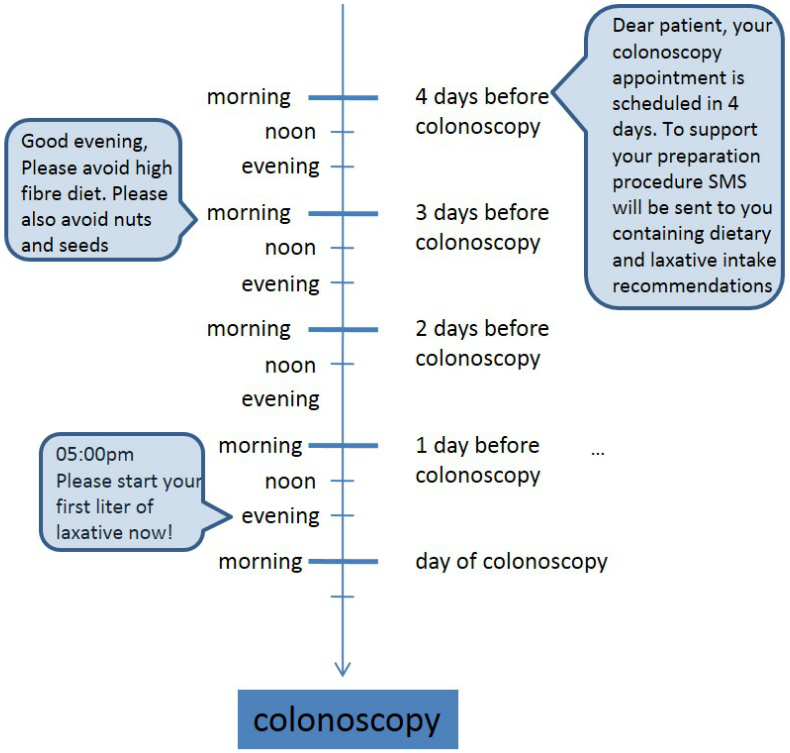
The program sends Web-based SMS text messages, adjusted to the specific date and time of colonoscopy appointment. Its guidance covers the patient starting 4 days before colonoscopy with behavioral and dietary recommendations. At the specified time, the patient is reminded to start laxative intake and consume recommended amount of clear fluids.

Text Message Contents

As characters for SMS text messages are limited, some text messages are split into two. First, second, and third messages contain a welcome message and general information about colonoscopy preparation and safety advices (eg, car driving is prohibited after colonoscopy with sedation). Dietary information is provided for each day starting with the fourth SMS text message 3 days before colonoscopy. On the day before colonoscopy the patients receive in total 6 SMS text messages containing information about starting and continuing of laxative intake and dietary recommendations. The last SMS text message is automatically sent 1 hour before the colonoscopy appointment. For graphical scheme of the SMS text messaging reminder system, please see Figure 1.

After developing the SMS text messaging system, a prospective study was conducted at the II. Medizinische Klinik, Klinikum rechts der Isar, Technische Universität München, Munich. The study protocol was approved by the local ethics committee. Informed consent was obtained from the study participants.

Figure 1. Graphical workflow of the text messaging (short message service, SMS)-guided colonoscopy preparation; examples of SMS text messages.



Colonoscopy Preparation Scheme

At our institution, colonoscopy preparation standard for all patients is a regular polyethylene glycol (PEG)–based split-dose regimen (MOVIPREP; Norgine, England). Explanations of the regular colonoscopy preparation procedure are given during informed consent discussion several days before endoscopy by the endoscopist. Furthermore, a leaflet containing detailed diet and preparation recommendations is given to every patient before colonoscopy. For analysis of quality assurance, colonoscopy preparation is routinely measured by the Boston Bowel Preparation Scale (BBPS) [6]. The BBPS was developed to limit interobserver variability in the rating of bowel preparation quality, while preserving the ability to distinguish various degrees of bowel cleanliness. A 4-point scoring system is applied to the 3 broad regions of the colon: the right colon including the cecum and ascending colon, the transverse colon including the hepatic and splenic flexures, and the left colon including the descending colon and rectum. Every segment receives a segment score from 0 to 3 (0, minimum cleanliness to 3, maximum cleanliness). These segment scores are summed for a total BBPS score with a possible achievable total count of 9 points (3 for each colon region: left colon, transverse colon, and right colon). The BBPS reflects a better discrimination in colon regions and quality of colon preparation in comparison with other preparation scales. Previous studies have shown that a BBPS score of 5 is an important clinical threshold [6,7].

Feasibility Study Performance

A total number of 20 patients undergoing outpatient colonoscopy were included in the SMS text messaging–supported colonoscopy preparation group from November 2013 to January 2014. Inclusion criteria were outpatient colonoscopy, written informed consent, age >18 years, and mobile phone with a SIM (subscriber identity module) card of a German (national) mobile phone provider. Exclusion criteria were phenprocoumon therapy, diabetes mellitus with insulin therapy, pregnancy, recent neurologic illnesses, and reported electrolyte disturbances.

Date and time of colonoscopy and mobile phone numbers of the SMS study group participants were collected and entered into a fully automated SMS text messaging reminder system (SmartPatient GmbH, Munich, Germany). Participants of the SMS study group additionally received the aforementioned SMS text messages. The information contained was in accordance with the colonoscopy preparation leaflet, which was handed to the patient in advance. No additional contents were provided by the short messages (Figure 1).

For safety reasons the study participants were informed to follow the instructions on the provided leaflet in case of delayed or missing SMS text messages or unclear information about the preparation steps.

A questionnaire was given to the SMS study group participants, containing the following topics to be evaluated by a numeric rating scale (NRS) or yes/no answers: (1) history of prior colonoscopies (experience in bowel preparation), (2) SMS text message received or not, (3) extent of discomfort caused by the colonoscopy preparation procedure, (4) whether the information provided by SMS text message was helpful, (5) whether information provided by SMS text message was inhibitory toward preparation, (6) whether the patient would favor the use of SMS text messaging–supported colonoscopy preparation again, and (7) whether patients would recommend the SMS text messaging reminder system to friends or family members undergoing colonoscopy.

Satisfaction with the SMS text messaging system was assessed using an NRS from 1 to 10 (1, not helpful to 10, very helpful; 1, not inhibitory to 10, very inhibitory).

For reasons of comparison, BBPS data of 20 patients who underwent outpatient colonoscopy at our institution during the study period, matching in age, sex, and indication for colonoscopy, were compared with the study data.

The primary end point was the feasibility of the automated SMS text messaging reminder system for colonoscopy preparation assessed as stable function of the system, technical success, and consecutive feasibility of colonoscopy preparation and colonoscopy.

Secondary end points included patient satisfaction (perception of the message contents as helpful or as a hindrance, whether the reminder system would be chosen for next colonoscopy again, and whether the SMS text messaging system could be recommended to friends and relatives) and quality of bowel preparation assessed by the BBPS as rated by the endoscopist. We defined a threshold of a BBPS score of 5 or higher for a sufficient bowel preparation for colonoscopy [6,7].

Statistical Analysis

A total of 20 patients were planned to be included in the feasibility study. Descriptive statistics were computed for all variables to provide means and standard deviations (SDs) for continuous variables and frequencies for categorical variables. Total BBPS scores were calculated (SMS study group and controls). *P* values correspond to Mann-Whitney *U* test. The results for colon preparation were dichotomized to adequate preparation (BBPS total score 5-9) and inadequate colon preparation (BBPS total score <5). All statistical analyses were performed with statistical software GraphPad Prism (GraphPad Software Inc, La Jolla, CA, USA).

Results

Preevaluation of Mobile Phone Usage

For the questionnaire study 300 patients were analyzed. Mean age was 61.4 (standard error of the mean, SEM 18.5) years. There were 133 female participants and 167 male participants (male to female ratio was 1.3:1). In total there were 119 patients with smartphones (39%), 128 with mobile phones (43%), and 53 patients (18%) without a mobile phone. Patient characteristics and results are presented in Table 1.

Table 1. Patient characteristics of mobile phone usage.

Characteristic	Mobile phone	Smartphone	None
Number of patients, n (%)	128 (43)	119 (39)	53 (18)
Sex (male/female)	64/64	76/43	27/26
Age in years, mean (SEM[a])	65.8 (12.9)	47.3 (15.5)	82.2 (8.6)

[a] SEM: standard error of the mean.

Text Messaging System Feasibility Study

Patient Characteristics

For the study a total of 20 patients who got an appointment for outpatient colonoscopy were included. Male to female ratio was 1:1 (10 males, 10 females). Data from outpatient colonoscopies were collected as control (Table 2). Controls were taken from the colonoscopy database of the hospital. Outpatient colonoscopies performed during the recruiting period of the study were included. Matching criteria were as follows: age (±1 year), sex, first or previous colonoscopies (in our hospital), and preparation with PEG (prescription). In case of several matching patients, data of the patient with the highest BBPS result were taken from the database to avoid further bias.

Primary End Point

The text messages were received by 19 of 20 participants (Table 2). For 1 participant an invalid SIM card by mobile phone provider caused a 20-minute delay in every SMS text message delivered.

Secondary End Points

No total BBPS score lower than 5 points was recorded in the SMS study group, whereas 1 patient had a BBPS score of <5 in the control group. Mean BBPS score of the SMS study group was 7.3 (SEM 0.28) in comparison with mean 6.4 (SEM 0.35) in the control group, which is a significant improvement, calculated by Mann-Whitney *U* test (*P*=.035 for difference; Figure 2). Regarding the left, transverse, and right colon regions, there was a certain improvement in the BBPS score of all colon regions (Figure 3). The mean BBPS score of the SMS study group for the left colon was 2.5 (SEM 0.13), which was higher in comparison with mean 2.2 (SEM 0.12) in the control group; however, the improvement was not statistically significant (*P*=.0816 for difference; Figure 3). The mean BBPS score of the SMS group for the transverse colon was 2.4 (SEM 0.11), which was higher in comparison with mean 2.1 (SEM 0.11) in the control group; however, the improvement was not statistically significant (*P*=.2482 for difference; Figure 3).The mean BBPS score of the SMS group for the right colon was 2.4 (SEM 0.11), higher in comparison with mean 2.0 (SEM 0.14) in the control group, which is a significant improvement (*P*=.0483 for difference; Figure 3).

All study participants of the SMS group stated they would use the SMS text messaging reminder system again. Of 20 participants, 19 stated they would recommend the system to their friends and relatives, whereas 1 participant was willing to recommend the SMS text messaging system only if it was a step toward a colonoscopy preparation app for smartphones. When asked if the reminder system was helpful to get the colonoscopy preparation done, patients reported an average NRS score for usefulness of 7.8 (SD 2.2, n=18). On the contrary,

the SMS text messaging reminder system was not found to be inhibitory by an average NRS score for inhibitory effect of the text message of 1.1 (SD 0.31, n=19; Table 2).

Table 2. Patient characteristics.

Characteristic	SMS group	Control group
No. of patients	20	20
Sex (male/female)	10/10 (50%/50%)	10/10 (50%/50%)
Age in years, mean (SD[a])	46.5 (12.6)	46.5 (13.0)
Method of bowel preparation, PEG[b] solution no. (%)	20 (100.0)	20 (100.0)
First colonoscopy (yes/no)	13/7 (65%/35%)	12/8 (60%/40%)
SMS[c] received and followed instructions (yes/no)	19/1 (95%/5%)	N/A[d]
Preparation procedure is perceived as stressful[e], mean (SD[a])	5.6 (2.4)	N/A
SMS information perceived as helpful information[f], mean (SD)	7.8 (2.2)	N/A
SMS information perceived as hindrance[g], mean (SD)	1.1 (0.31)	N/A
Reuse of SMS reminder system for another colonoscopy (yes/no)	20/0 (100%/0%)	N/A
Recommendation of SMS system to friends and relatives (yes/no)	19/1 (95%/5%)	N/A

[a] SD: standard deviation.

[b] PEG: polyethylene glycol.

[c] SMS: short message service.

[d] N/A: not assessed.

[e] Evaluation: 1, no stress to 10, very stressful.

[f] Evaluation: 1, not helpful to 10, very helpful.

[g] Evaluation: 1, not a hindrance to 10, great hindrance.

Figure 2. Average Boston Bowel Preparation Scale (BBPS) score in the short message service (SMS) study group was significantly higher in comparison with the control group (7.3 vs 6.4, *P*=.035). BBPS: 0, minimum to 9, maximum.

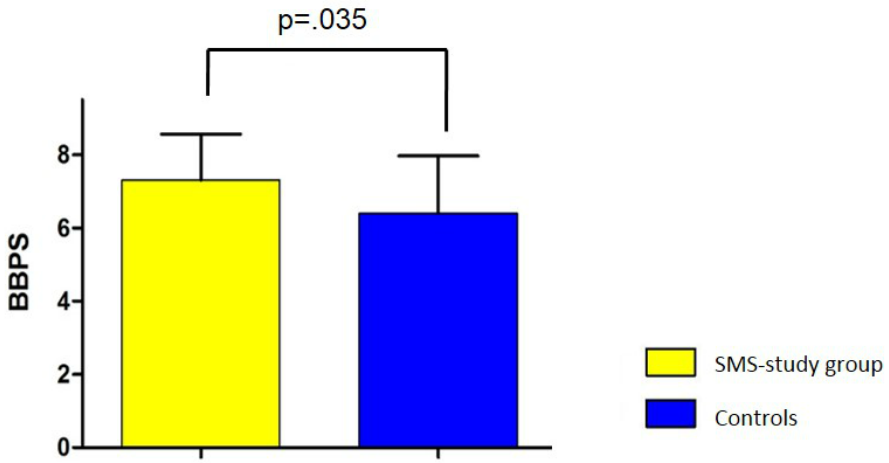
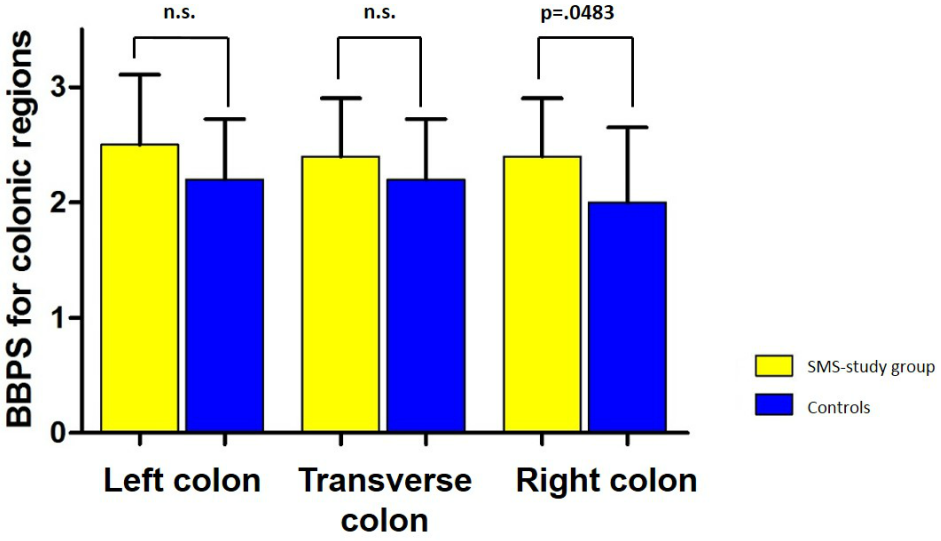


Figure 3. The average Boston Bowel Preparation Scale (BBPS) score (0, minimum to 3, maximum) split for each colon region. SMS: short message service; n.s.: not significant.



Discussion

Adequate bowel preparation is a prerequisite for an effective colonoscopy. Inadequate bowel preparation occurs in 15% to more than 20% of all examinations [1,2]. It has been reported that many patients have problems in handling the laxative and following dietary recommendations before the colonoscopy appointment [8-12]. Patient compliance is generally reduced in case of unclear instructions or uncertainty in therapy recommendations. These data stress the importance of proper patient education [5]. The approach of using new media that are spreading among the population is still poorly examined. We now report the development and testing of an automated Web-based SMS text messaging system to guide the patient through colonoscopy preparation.

Preevaluation to Assess Mobile Phone Usage

Preevaluation performed to assess mobile phone usage in our patient population revealed that the majority of our patients are already equipped with mobile phones and use them in everyday life. Therefore the approach to include new media such as SMS text messaging in colonoscopy preparation could be quite reasonable. The mean age of patients with a mobile phone, in comparison with smartphone users, was much higher; therefore we arrived at the conclusion that the population undergoing screening colonoscopy is still better supported by a mobile phone (SMS)–derived solution.

Text Messaging–System Development and Feasibility Study

This study showed that an automated, Web-based SMS text messaging reminder system is feasible for outpatients. Technical success (SMS text messages were sent and received in time, the Web-based SMS text messaging system functioned satisfactorily, no remarkable bugs had to be fixed during the study) was achieved in 19 of 20 patients. In the case of 1 patient a technical problem was caused by an invalid SIM card from the mobile phone provider. There was a 20-minute delay in delivering each SMS text message. Importantly, colonoscopy was performed without problems in all patients of the SMS study group.

Patients perceived the SMS text messaging service as very helpful and stated that they would recommend its use to friends and relatives.

Moreover, we could observe a tendency toward improvement in the quality of the preparation procedure. When compared with control subjects who followed standard verbal instructions and a leaflet for bowel preparation, the SMS study group participants achieved better, but statistically significant, results of bowel cleansing. This was reflected by a higher BBPS count. A BBPS score of <5 is generally considered to be an insufficient preparation result, which leads to the recommendation to repeat the examination [6,7]. In comparison with the control group, none of the SMS study group participants had a BBPS score of <5.

Several approaches toward improvement of patient guidance and education have been evaluated in the past. A visual aid based on cartoons as well as video education or telephone-based reminder systems improved patient satisfaction and bowel preparation quality [13-16]. All approaches had specific limitations. For example, video-based education is stationary and needs additional equipment (eg, DVD player or television). A telephone-based reminding system or an existing SMS text messaging–based system consists only of a single (manual) phone call or SMS text message the day before the colonoscopy.

A continuous patient guidance and personal contact throughout the days before colonoscopy would be the most favorable situation for improving colonoscopy preparation results. Therefore, we believe that inclusion of dietary and behavioral recommendations instead of only reminding the patient to start laxative intake is necessary.

Nowadays, mobile phones, but not yet smartphones, are widely used even among the older population. Short message service is already an established way of communication. By using an automated SMS text messaging reminder system, a closer

guidance and education of the patient can be ensured. This allows repeating the information for the most crucial steps of colonoscopy preparation in a time-adjusted manner. In order to save most convenient usability for the patient, in general different languages are possible to be used in SMS for colonoscopy preparation. Translation of the text messages into foreign languages can even open up higher participation in colon cancer screening.

Study Limitations

The study is subject to some limitations. As the automated SMS text messaging–aided colonoscopy preparation system was newly developed, the design of the study was a single-center feasibility study with a consecutive, very small number of study participants. The extended exclusion criteria caused a long period of patient recruitment and the results are very preliminary. The real effect of an automated SMS text messaging reminder system on the quality of bowel cleansing has, therefore, to be shown in larger randomized studies. We also understand that statistics are very limited because of the small number of study participants, and therefore conclusions regarding improvement of bowel cleanliness are also very limited.

However, we would like to point out that automated SMS text messaging guidance covering the whole period of colonoscopy preparation could be a new approach to achieve a higher degree of bowel cleanliness.

Conclusions

In conclusion, an automated SMS text messaging reminder system starting 4 days before colonoscopy appointment, containing dietary recommendations and recommendations for laxative intake, is technically feasible and helpful during colonoscopy preparation. It could help to ensure procedure quality and improvement of patient comfort.

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Conflicts of Interest

Software support for the study was received from SmartPatient GmbH, Munich, Germany. SmartPatient GmbH did not participate in study design, data collection, data analysis, or manuscript preparation.

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Abbreviations

BBPS: Boston Bowel Preparation Scale
NRS: numeric rating scale
SD: standard deviation
SEM: standard error of the mean
SIM: subscriber identity module
SMS: short message service
PEG: polyethylene glycol

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Original Paper

A Mobile Health Lifestyle Program for Prevention of Weight Gain in Young Adults (TXT2BFiT): Nine-Month Outcomes of a Randomized Controlled Trial

Margaret Allman-Farinelli[1], PhD, FDAA; Stephanie Ruth Partridge[1], BSc (Hon), APD; Kevin McGeechan[2], PhD; Kate Balestracci[1], MS; Lana Hebden[1], PhD, APD; Annette Wong[1], PhD, APD; Philayrath Phongsavan[3], PhD; Elizabeth Denney-Wilson[4], PhD, RN; Mark F Harris[5], MD, FRACGP; Adrian Bauman[3], PhD, FAFPHM

[1]School of Life and Environmental Sciences, Charles Perkins Centre, University of Sydney, University of Sydney, Australia

[2]School of Public Health, University of Sydney, University of Sydney, Australia

[3]School of Public Health, Charles Perkins Centre, University of Sydney, University of Sydney, Australia

[4]School of Nursing, University of Technology Sydney, Sydney, Australia

[5]Centre for Primary Health Care and Equity, University of New South Wales, Kensington, Australia

Corresponding Author:
Margaret Allman-Farinelli, PhD, FDAA
School of Life and Environmental Sciences
Charles Perkins Centre
University of Sydney
Building D17
University of Sydney, 2006
Australia
Phone: 61 90367045
Fax: 61 90670602
Email: margaret.allmanfarinelli@sydney.edu.au

Abstract

Background: The unprecedented rise in obesity among young adults, who have limited interaction with health services, has not been successfully abated.

Objective: The objective of this study was to assess the maintenance outcomes of a 12-week mHealth intervention on prevention of weight gain in young adults and lifestyle behaviors at 9 months from baseline.

Methods: A two-arm, parallel, randomized controlled trial (RCT) with subjects allocated to intervention or control 1:1 was conducted in a community setting in Greater Sydney, Australia. From November 2012 to July 2014, 18- to 35-year-old overweight individuals with a body mass index (BMI) of 25-31.99 kg/m2 and those with a BMI ≥ 23 kg/m2 and a self-reported weight gain of ≥ 2 kg in the past 12 months were recruited. A 12-week mHealth program "TXT2BFiT" was administered to the intervention arm. This included 5 coaching calls, 96 text messages, 12 emails, apps, and downloadable resources from the study website. Lifestyle behaviors addressed were intake of fruits, vegetables, sugar-sweetened beverages (SSBs), take-out meals, and physical activity. The control group received 1 phone call to introduce them to study procedures and 4 text messages over 12 weeks. After 12 weeks, the intervention arm received 2 further coaching calls, 6 text messages, and 6 emails with continued access to the study website during 6-month follow-up. Control arm received no further contact. The primary outcome was weight change (kg) with weight measured at baseline and at 12 weeks and self-report at baseline, 12 weeks, and 9 months. Secondary outcomes were change in physical activity (metabolic equivalent of task, MET-mins) and categories of intake for fruits, vegetables, SSBs, and take-out meals. These were assessed via Web-based surveys.

Results: Two hundred and fifty young adults enrolled in the RCT. Intervention participants weighed less at 12 weeks compared with controls (model β=−3.7, 95% CI −6.1 to −1.3) and after 9 months (model β=− 4.3, 95% CI − 6.9 to − 1.8). No differences in physical activity were found but all diet behaviors showed that the intervention group, compared with controls at 9 months, had greater odds of meeting recommendations for fruits (OR 3.83, 95% CI 2.10-6.99); for vegetables (OR 2.42, 95% CI 1.32-4.44); for SSB (OR 3.11, 95% CI 1.47-6.59); and for take-out meals (OR 1.88, 95% CI 1.07-3.30).

Conclusions: Delivery of an mHealth intervention for prevention of weight gain resulted in modest weight loss at 12 weeks with further loss at 9 months in 18- to 35-year-olds. Although there was no evidence of change in physical activity, improvements in dietary behaviors occurred, and were maintained at 9 months. Owing to its scalable potential for widespread adoption, replication trials should be conducted in diverse populations of overweight young adults.

Trial Registration: Australian and New Zealand Clinical Trials Registry (ANZCTR): ACTRN12612000924853; (Archived by WebCite at http://www.webcitation.org/6i6iRag55)

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KEYWORDS

young adult; weight gain prevention; mHealth; telehealth; fruit; vegetables; take-out foods; sugar-sweetened beverages; physical activity

Introduction

The World Health Organization (WHO) declared a global obesity epidemic in 1998, but to date, progress in reversing or even halting increases in prevalence has failed [1]. There is some evidence that the rise in childhood obesity has plateaued in countries such as the United States and Australia [2]. However, young adulthood is an important population group that has been largely neglected and their steep trajectory of weight gain is mostly unrecognized [3,4]. This is of concern as incident obesity at a younger age carries increased risk of mortality from and morbidities of cardiovascular disease, type 2 diabetes, some cancers, and osteoarthritis among others [5-8]. Failure to address the weight gain of young adults may limit the success of childhood prevention programs.

Systematic literature reviews in recent years have drawn attention to the limited evidence base for successful interventions in 18- to 35-year-olds [9]. Many studies have had small numbers of subjects but have shown no potential for translation and scale-up to the community [10]. Rather, the use of young adults as subjects has been coincidental as college-based researchers find it easy to recruit on campus [11].

The life cycle phase termed “emerging adulthood” (18-24 years) signifies the transition from adolescence to leaving school, going to college or finding a job, and increasing independence [12]. It has been identified that this might be a window of opportunity to improve health behaviors as they become more receptive as the rebellion of teenage years is left behind [13]. Young adults need healthy lifestyles to both avoid obesity-related diseases in middle age and to protect their future progeny [14-16].

In 2010, the United States acknowledged young adults as a group requiring intervention for the prevention of weight gain with the award of research funding for the seven EARLY studies targeting 18- to 35-year-olds. [17]. Decreases in physical activity and continued high consumption of sugar-sweetened beverages (SSBs) and food prepared outside home are common lifestyle behaviors in young adults across many western nations [18]. With almost universal ownership of mobiles phones, (91% of young adults in the United States and 95% in Australia), this communication channel could be exploited for intervention delivery, referred to as mHealth [19]. Mobile phones have many features that can be used to provide education and counseling, such as text messaging, apps, and Internet access, in addition to the traditional voice call function.

Here we describe the effectiveness of a 9-month randomized controlled trial (RCT) of an mHealth program for 18- to 35-year-olds conducted in Australia, which aimed to improve lifestyle behaviors [20]. We hypothesized that those overweight young adults who received our 12-week “TXT2BFiT” program followed by a 6-month low-dose maintenance phase would gain less weight compared with those who received minimal intervention.

Methods

Study Population

Participants were aged 18-35 years and lived in Greater Sydney, Australia. All participants provided written informed consent and the study was approved by the institutional human ethics review board [20]. A detailed description of the recruitment process has been published previously [21]. In brief, subjects were recruited using mailings from primary care physicians, print media including posters, mass delivery of brochures and newspaper advertisements, and electronic media [21]. No racial or gender bias existed in the recruitment process.

Study Design

The study was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12612000924853) and the study protocol published beforehand [20]. This study is a parallel two-arm RCT with subjects randomized 1:1. The deviation from the original protocol was that recruitment was extended from letters of invitation sent from primary care practices to include print and electronic media advertisements [21]. Regardless of recruitment method, all participants were required to visit a primary care physician to enter the study. Only 250 participants were recruited (due to slower-than-expected recruitment) rather than the 354 participants in the protocol [21].

Enrolment took place from November 2012 until July 2014. Participants completed an online screener to assess eligibility and those who met inclusion criteria attended a paid consultation with a primary care physician to verify medical fitness to participate. Participants were then allocated to one of two study arms, control or “TXT2BFiT” intervention, using a stratified block design according to sex and the primary care practice responsible for confirming eligibility. The randomized block contained block sizes 2, 4, and 6. A randomization list was generated using RAND.exe [22] and held centrally by the statistician. When an individual was recruited, the statistician

assigned the treatment arm but was blind to intervention status. Other researchers involved in measurement and analysis were also blinded. Participants had their treatment arm concealed but were aware of the intensity of intervention received [20].

Eligibility criteria included age between 18 and 35 years, a body mass index (BMI) of 25 to 31.9 kg/m^2, or 23 to 24.9 kg/m^2 and > 2 kg self-reported weight gain in preceding 12 months [20]. Ownership of a mobile phone and access to the internet at least once a week was required for intervention delivery. Subjects had to be failing to meet one or more of the key behaviors for modification which were less than 2 serves fruit daily; less than 5 serves vegetables daily; more than 1 high-energy, high-fat take-out meal weekly; more than or equal to 1 liter SSBs weekly; less than 60 minutes of moderate physical activity daily. Exclusion criteria were pregnancy or planning to fall pregnant within 9 months, participation in an alternate weight loss program, weight loss of > 10 kg in preceding 3 months, medications that caused > 2 kg weight gain, disordered eating or medical contraindication, and non-English speaking [20].

The mHealth program ran for 12 weeks after which participants entered a maintenance intervention phase for an additional 6 months.

Twelve-Week "TXT2BFiT" Program

The program promotes the consumption of core food groups and limitation of energy-dense nutrient-poor discretionary foods. Key behaviors for change are fruit and vegetable intake to meet recommended amounts (behavior 1); high-fat, high-energy take-out meals (behavior 2) and SSBs (behavior 3) are discouraged. In addition, participants are encouraged to achieve 60 minutes of physical activity daily (behavior 4), the upper level of Australian recommendations [23]. Participants allocated to the treatment arm received a multicomponent mHealth program. This included 5 coaching calls by a dietitian skilled in motivational interviewing. Goal setting and review were included in the coaching and modeled on control theory with their intake (input function) compared with recommended (comparator) and, therefore, provided feedback to improve their behavior (week 0, 2, 5, 8, 11) [24]. For each of the 4 key behaviors addressed, a staging algorithm based on the transtheoretical model was completed as part of the baseline survey by all participants [20,25]. This was used to generate a personalized set of messages (8 messages a week) from our bank of text messages to be sent over the 12-weeks. Messages were stratified by sex and whether the participant was in pre-contemplation, contemplation, preparation, action, or maintenance stages for each of the 4 behaviors. More cognitive messages were included if a behavior was in the early stage for change and messages were more behavioral if participant was in the action or maintenance stages for any given behavior. Twelve emails (once a week) were sent by the dietitian who offered coaching and repeated the information in the text messages with links to remind participants to use the other resources provided. After a coaching call, the goals set were reiterated in the emails sent by the dietitian.

Other components of the program were a comprehensive 18-page diet and nutrition booklet with physical activity guidelines and a website. This website gave access to 4 designer mobile phone apps for education and self-monitoring for each of the 4 key lifestyle behaviors addressed. Other resources were online weight tracker, printable charts such as "eating on a budget," "emergency meal tool kit," "meal planner," "seasonal guide to fruit and vegetables," "tips for take-outs," physical activity planner and "staying healthy over holidays;" and a blog facility for communication [26].

Control Program

A minimal intervention was delivered to controls, which included 4 text messages, 1 on each key behavior, over 12 weeks (fruit and vegetables, take-out meals, SSBs, and physical activity). Control participants also received a 2-page handout based on the Australian dietary guidelines and physical activity guidelines. They had access to a website (separate from the password-protected website of the intervention participants) that contained only the participant information sheet and the 2-page handout. An introductory phone call was made to each participant but no coaching was provided.

Six-Month Maintenance Phase

After the 12-week "TXT2BFiT" program, intervention participants received a low dose maintenance intervention. This consisted of monthly text messages and emails, and participants had continued access to the website. Two booster coaching phone calls at 5 and 8 months from baseline were included. Control participants had no further treatment contact during this period.

Measurements

The primary outcome was change in weight. All participants were weighed to the nearest 0.1 kg and had their height measured to the nearest 0.1 cm by their primary care physician at baseline according to a standard protocol. Participants were invited to be weighed by study personnel at the end of the 12-week trial [20]. Self-reported measures of body weight were collected at baseline, end of 12-week trial, and again at the end of 6-month maintenance (9 months) via the Web-based survey instrument. BMI was calculated. Following a standardized procedure, participants were provided with instructions on self-weighing by the dietitian.

Secondary outcomes were assessed using online surveys at baseline, the end of the 12-week trial, and the end of the 6-month maintenance. These included changes in fruit and vegetable intake (daily servings), SSBs (weekly intake), and weekly frequency of take-out meals assessed using short categorical questions. Change in frequency and minutes of physical activity were assessed using the short-form International Physical Activity Questionnaire (IPAQ). Details of the questions have been published previously [20]. A $AU10.00 gift voucher was given for completion of each survey and clinic attendance for weight measurement.

Demographic details were collected via the online questionnaire that included age, sex, postcode used to determine socioeconomic status (SES), language spoken at home, and the WHO-5 well-being questionnaire [20,27]. The delivery of the program was monitored by number of coaching calls completed,

number of emails and text messages delivered, and number of downloads of the mobile phone apps. Participants in the intervention were asked to reply to 22 text messages over the 9 months (16 in the first 12 weeks and 6 in the next 6 months). Both the 12-week and 9-month online surveys included questions on use of the program elements.

Sample Size Calculation

The sample size was calculated based on a difference of 2 kg between intervention and control groups, allowing for a standard deviation of 10 kg and a correlation of 0.8 of baseline weight and final weight. With 142 subjects in each arm, this difference could be detected with 80% power at $P<.05$ (two sided). To allow for a 20% drop out rate, the sample size was increased to 354 in total. As stated above, recruitment was ceased at 250 participants [21].

Statistical Analysis

Attrition bias was examined using *t* tests for continuous variables and chi-square tests for categorical variables. The baseline characteristics of completers and non-completers at 9 months within both the intervention and control groups were compared. The IPAQ was scored using standard methods to yield a continuous measure of reported physical activity minutes weekly (metabolic equivalent of task, MET-min) [28]. Differences between the experimental and control group over time in the continuous variables, such as body weight, BMI, physical activity, and WHO-5 outcomes, were estimated using linear mixed models, with an unstructured correlation matrix, adjusted for sex and primary care practice (fitted as fixed effects) and implemented with PROC MIXED. We examined plots of panel-studentized residuals which demonstrated normality and constant variance. Interaction between time and group was included in the model. Diet outcomes (fruit, vegetables, SSBs, and take-out meals) were analyzed using cumulative logistic regression models with general estimating equations (GEE) to account for correlation between time points and multiple imputations to account for missing values. Ten imputed data sets were created using chained equations utilizing baseline values and available data at 3 and 9 months, as well as participant baseline characteristics including sex, ethnic background (language spoken at home), recruitment practice, and allocation. This included odds of improvement in diet-related behaviors and odds of meeting suggested intakes of 2 serves fruit, 3 or more serves of vegetables, less than 500 mL of SSBs per week, and less than one take-out meal weekly. The effect of missing data was investigated as part of a sensitivity analysis using multiple imputation under the missing not at random (MNAR) assumption by searching for a tipping point that reverses the primary outcome conclusion [29]. Clinically plausible weight gains (fixed values) were added to randomly generated imputed values to investigate the impact at 3 month time-point and 9 month end point. Ten imputed data sets were created as described above. All analyses were performed with SAS (version 9.2 SAS Institute Inc. Cary NC, USA).

Results

Figure 1 displays the flow of participants through the trial. In all, 1181 attempts of the screener survey were recorded with 547 of these failing to complete screening. An additional 244 failed to meet the inclusion criteria and 138 eligible participants failed to complete the visit to the primary care physician and were not randomized. Two participants were randomized after census date.

One hundred and twenty-five participants were allocated to each arm. After the 12-week program, 110 intervention participants and 104 control participants completed the Web-based survey for assessment of outcomes. At completion of the maintenance phase, 97 intervention participants and 105 control participants completed the final online survey.

Table 1 summarizes the demographic characteristics and lifestyle behaviors of the population at baseline. Participants were mostly in the overweight BMI range, of higher SES, from English-speaking backgrounds, and tertiary educated. Approximately 3 in 5 participants were females and mean WHO-5 was just below middle of the scale of 25, indicating a tendency of poor well-being. Most participants failed to meet the criteria for fruits (2 serves), vegetables (3 serves), and take-out meals (more than 1 per week). Most participants consumed less than 500 mL of SSBs weekly and the mean total daily physical activity was approximately 55 minutes of moderate physical activity on each of the past 7 days; 51.6% met the national recommendation for 30 minutes of physical activity per day (48.8% intervention, 54.4% control). A comparison of those participants retained in the study versus those lost to follow-up after 9 months showed no significant differences by demographic characteristics neither for intervention nor for the control group.

Table 1. Characteristics and baseline behaviors of participants in the TXT2BFiT trial.

Characteristic		Intervention group (n=123)[a] mean (SD) or n (%)	Control group (n=125) mean (SD) or n (%)
Age in years, mean (SD)		28.1 (4.9)	27.2 (4.9)
Gender, n (%)			
	Female	73 (59.3)	79 (63.2)
Weight status			
	Normal BMI 23.0-24.9	24 (19.5)	33 (26.4)
	Overweight BMI 25.0-29.9	83 (67.5)	70 (56.0)
	Obese BMI 30.0-31.99	16 (13.0)	22 (17.6)
BMI (kg m^{-2}), median (IQR)		27.1 (3.7)	26.8 (4.2)
WHO-5 score		11.8 (4.7)	12.9 (4.5)
SES[b], n (%)			
	0-60	8 (6.5)	7 (5.6)
	61-80	28 (22.8)	17 (13.6)
	81-100 (highest)	87 (70.7)	101 (80.8)
Ethnic background, n (%)			
	English speaking	82 (66.7)	90 (72.0)
	Other[c]	41 (33.3)	35 (28.0)
Education, n (%)			
	High school or below	27 (22.0)	21 (16.8)
	Some tertiary education	22 (17.8)	25 (20.0)
	University degree	74 (60.2)	79 (63.2)
Fruit	< 2 serves per day	82 (66.7)	77 (61.6)
Vegetable	≤ 3 serves per day[d]	104 (84.6)	107 (85.6)
SSB [e]	≥ 500 mL per week	37 (30.1)	44 (35.2)
Take-out meals	> once per week	75 (60.9)	79 (63.2)
Physical activity	Total MET[f]-mins weekly	1620 (1581)	1647 (1475)

[a]Two participants had measured variables but did not complete baseline self-report survey.

[b]SES: socioeconomic status by quintile with the bottom three quintiles collapsed into one.

[c]European, Asian, Pacific Islander, and Arabic ethnicities collapsed.

[d]Australian recommendations are 5 serves per day but the World Health Organization recommendation of 3 is used here.

[e]SSB: sugar-sweetened beverages.

[f]MET: metabolic equivalent of task.

Table 2 presents body weight, BMI, and MET-minutes of physical activity per week for intervention and control groups. After the 12-week program the intervention participants weighed 3.7 kg (95% CI −6.1 to −1.3, *P*=.003) less than controls and after maintenance, 9 months from baseline, the intervention group weighed 4.3 kg (95% CI −6.9 to −1.8) less than controls (*P*=.001). The changes in BMI equated to a difference of 0.56 kg/m^2 (95% CI −1.22 to 0.09, *P*=.093) after the 12-week program and 0.78 kg/m^2 (95% CI −1.53 to −0.02, *P*=.044) at end of maintenance stage. Sensitivity analyses outlined above generated consistent findings for the primary outcome, with the addition of up to 2.4 kg at 3 months and 7.2 kg at 9 months to the imputed values. Although the intervention improved their moderate physical activity by 12 minutes per day more than the controls at 12 weeks, the differences were not significant and disappeared by 9 months. The WHO-5 score showed improvement in both groups with no significant differences between them. The mean increase in both groups was clinically meaningful, with the mean score above the cut point of 13 indicating improved well-being.

Odds ratios comparing the odds for improving intake of fruit, vegetables, SSBs, and take-out meals for intervention and

control groups are reported in Table 3. After the 12-week program, the odds that the intervention group improved intake compared to the control group were significantly greater for vegetables (*P*=.006), SSBs (*P*=.024), and take-out foods (*P*=.013). At the conclusion of maintenance stage, the intervention group had greater odds of maintaining improvements in all 4 diet variables. At the end of the program and the end of maintenance, the intervention group had greater odds of meeting suggested intakes for all dietary variables (Table 4).

Table 2. Comparison of self-reported weight, BMI[a], and physical activity in intervention (n=123) versus control (n=125) at baseline, end of program (3 months), and end of maintenance periods (9 months).

	Baseline=0 months, mean (SD)[b,c]		End of program=3 months, mean difference (SD)[c]			End of maintenance=9 months, mean difference (SD)[c]		
	TXT2BFiT	Control	TXT2BFiT	Control	Model β (95% CI)	TXT2BFiT	Control	Model β (95% CI)
Weight, kg								
	78.4 (11.2)	79.3 (12.6)	−2.2 (3.1)	−0.23 (2.3)	−3.7 (−6.1 to −1.3) *P*=.003	−3.8 (4.9)	−0.80 (3.7)	−4.3 (−6.9 to −1.8) *P*=.001
BMI, kg/m^2								
	27.3 (2.3)	27.0 (2.7)	−0.76 (1.0)	−0.08 (0.78)	−0.56 (−1.22 to 0.09) *P*=.093	−1.30 (1.7)	−0.26 (1.28)	−0.78 (−1.53 to −0.02) *P*=.044
Physical activity, MET-min								
	1620 (1581)	1647 (1475)	625 (1932)	302 (1411)	333 (−206 to 871) *P*=.225	872 (1918)	797 (2115)	70 (−474 to 614) *P*=.801
Physical activity, days								
	6.6 (3.3)	7.4 (3.8)	2.1 (3.8)	0.5 (3.7)	1.0 (0.0 to 2.0) *P*=.050	2.1 (4.3)	1.3 (4.4)	0.2 (−0.8 to 1.3) *P*=.679
WHO-5 score								
	11.8 (4.7)	12.9 (4.5)	3.2 (4.7)	1.2 (4.7)	0.9 (−0.4 to 2.1) *P*=.176	3.4 (4.5)	1.4 (5.2)	0.8 (−0.5 to 2.1) *P*=.202

[a]BMI: body mass index.

[b]SD: standard deviation.

[c]Mean difference between groups (95% confidence intervals) adjusted for practice and sex

Monitoring of intervention delivery showed that 92% of coaching calls were completed during the 12-week program and 81% during 6-month maintenance period. All emails were delivered and for the text messages, 98% were delivered during the first 12 weeks and 96% during the 6-month maintenance. During the 12-week program, 53% of participants replied to more than half the text messages but only 40% replied during the maintenance phase. All participants reported using the text messages at 12 weeks and 60% at 9 months. Fifty-two percent of participants downloaded the physical activity app, 43% downloaded the fruit and vegetable app, and 31% the beverages app [30]. The data on downloads of the take-out app could not be determined. The company hosting the website made changes that lead to a temporary loss of data from this app but it did not affect the other three.

Table 3. Odds ratios (95% confidence intervals) of improved intakes[a] for TXT2BFiT intervention versus control post-intervention (3 months) and post-maintenance (9 months) adjusted for practice and sex.

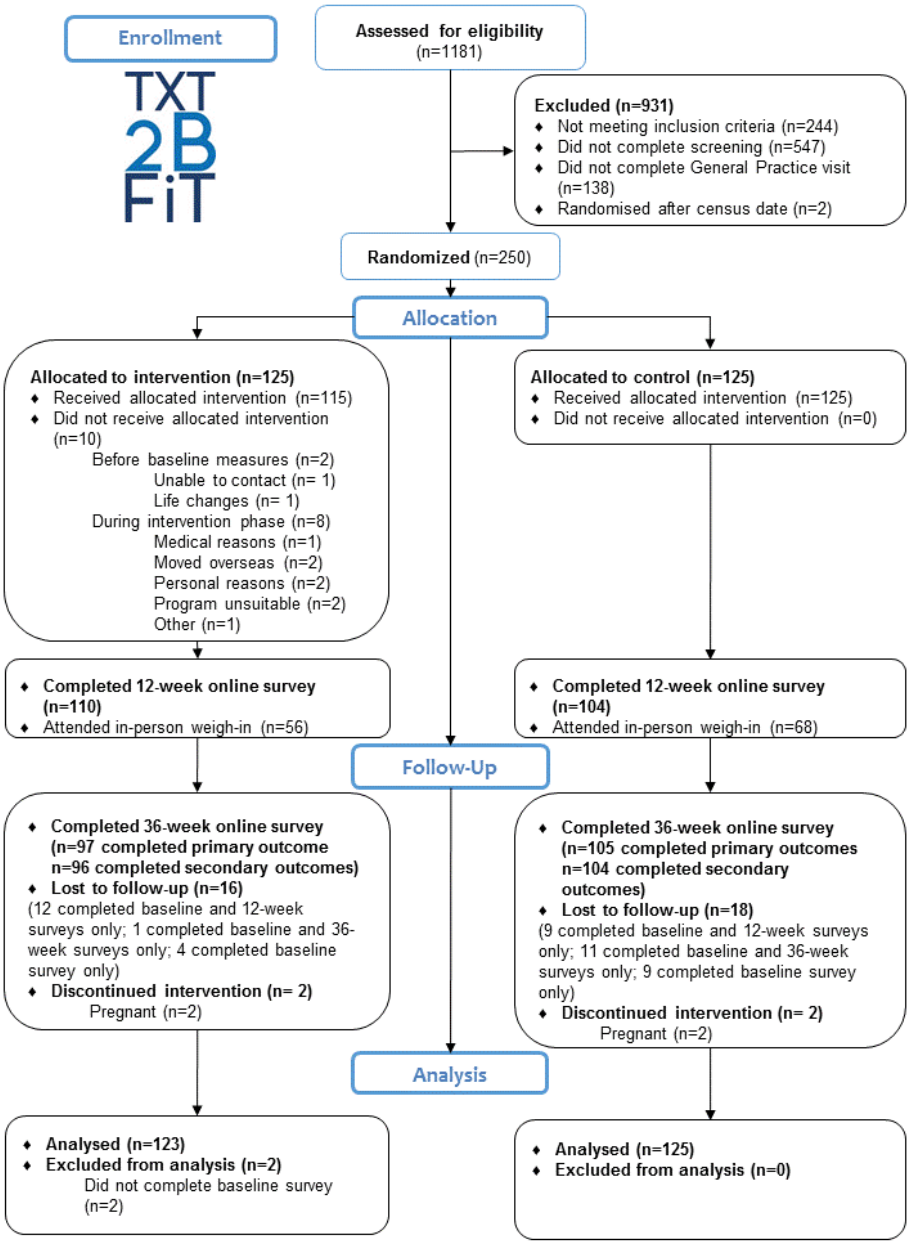
Phase		Fruit[a]	Vegetables[a]	Sugar-sweetened beverages[a]	Take-out meals[a]
Post intervention, time=3 months					
	Control	1.00 (reference)	1.00 (reference)	1.00 (reference)	1.00 (reference)
	TXT2BFiT	1.31 (0.79-2.15) *P*=.292	2.03 (1.23-3.35) *P*=.006	1.67 (1.07-2.61) *P*=.024	2.16 (1.18-3.95) *P*=.013
Post maintenance, time=9 months					
	Control	1.00 (reference)	1.00 (reference)	1.00 (reference)	1.00 (reference)
	TXT2BFiT	2.38 (1.41-4.01) *P*=.001	1.94 (1.19-3.16) *P*=.008	1.74 (1.10-2.77) *P*=.018	1.98 (1.17-3.34) *P*=.010

[a]Odds ratios were estimated using proportional odds models. Lower odds ratios, but greater than 1, were observed for the most improved categories.

Table 4. Odds ratios (95% confidence intervals) of meeting recommendations for TXT2BFiT intervention versus control post-intervention (3 months) and post-maintenance (9 months) adjusted for practice and sex.

Phase	Fruit ≥ 2 serves	Vegetables ≥ 3 serves	Sugar-sweetened beverages < 500 mL per week	Take-out meals < one per week
Post intervention time=3 months				
Control	1.00 (reference)	1.00 (reference)	1.00 (reference)	1.00 (reference)
TXT2BFiT	1.84 (1.01-3.34) *P*=.046	2.05 (1.16-3.62) *P*=.014	4.77 (1.96-11.62) *P*=.001	2.37 (1.21-4.63) *P*=.012
Post 6 maintenance time=9 months				
Control	1.00 (reference)	1.00 (reference)	1.00 (reference)	1.00 (reference)
TXT2BFiT	3.83 (2.10-6.99) *P*=.001	2.42 (1.32-4.44) *P*=.005	3.11 (1.47-6.59) *P*=.003	1.88 (1.07-3.30) *P*=.028

Figure 1. Flow of participants through the 9-month trial.



Discussion

This is one of the first trials of a multicomponent mHealth program for delivery to young adults with demonstrated maintenance of weight management and nutrition-related behavior change after the 12-week program. As hypothesized, the TXT2BFiT program prevented weight gain [25] leading to weight loss that can be maintained after 6 months follow-up

with minimal support. The use of mHealth to deliver effective lifestyle health promotion shows promise to halt the rising incidence of obesity during young adulthood—a group recognized as difficult to reach. The ubiquitous use of mobile phones by this age group allows for a number of communication channels to be used to deliver multicomponent programs.

The 12-week TXT2BFiT program led to additional positive health benefits through maintenance of improved diet behaviors at 9 months from baseline. This is the likely explanation for the 6-month maintenance of weight loss. In addition, increasing fruit and vegetable intake has benefits beyond weight management, in protection against cardiovascular disease and stroke and certain cancers [31-33]. In the past decade, consumption of SSBs has been associated with not only weight gain but also cardiovascular disease and type 2 diabetes [34]. The age group targeted here is the largest consumer of fast food meals among adults [35]. Such food is inevitably high in deleterious nutrients such as saturated fat and sodium, and higher frequency of intake is associated with type 2 diabetes in Australian young adults [36]. The intervention failed to produce increases in physical activity compared with control. Both groups appeared to have higher amounts of physical activity at 3 and 9 months but with wide variation. In previous research in a similar group of younger adults, 75% reported at least 150 minutes of moderate physical activity per week but most wanted to increase their physical activity [37]. This is higher than that in the current trial, with 51.6% of participants meeting national physical activity recommendations. The controls were sufficiently motivated to enroll in the study and likely had the capability and opportunity to increase their physical activity without intervention input. It is also of note that the controls did not gain weight during the 12-week program or at 9 months.

A number of other trials using new technologies have been conducted in young adults in the United States [17]. The CITY study compared treatment using 6 face-to-face group sessions followed by monthly phone calls for 24 months (PC), with both an intervention delivered via a mobile phone app and a control group [38]. Weight measurements in the 18- to 35-year-olds indicated a significant loss by the PC group compared with control and app group at 6 months but no difference between app and control groups. By 12 months, all differences disappeared [38].

This study was different from other studies in that the current intervention included 5 short coaching calls in the 3-month intensive phase as a component of the mHealth intervention. In our former pilot RCT to assess the feasibility of delivering the intervention in 50 young adults, we found no difference in weight loss between groups at 12 weeks because both reduced their weight [39]. The extra communication component in this study was the addition of short coaching calls. This allowed more personalized feedback for goal setting and review whereby their performance against a recommended behavior such as 2 daily serves of fruit was used to set goals to work toward the achievement of the target intake. It adds an additional cost to the program that amounted to approximately AU $45 per participant and cost-effectiveness comparisons with totally electronically delivered and traditional face-to-face intervention warrant further research. However, as discussed below, few electronic or entirely app-based interventions demonstrate effectiveness.

Other studies in young adults have used Web-based or email programs. Kattelmann et al delivered a 10-week Web-based intervention to 1639 US college students addressing healthy eating, physical activity, stress, and weight management in an RCT, and assessed post-intervention effects and 12-month maintenance. While both diet and physical activity behaviors improved, no changes in weight occurred and the effects were not maintained 12 months later [40]. Schweitzer et al delivered an adaptation of A Lifestyle Intervention via Email, the ALIVE program, for 24 weeks in a pilot RCT to 148 college students aged 18-20 years. While no differences in body weight were found, the intervention participants increased their intake of fruits as a snack and marginally decreased the percentage energy from saturated fat [41]. Park et al conducted a Web-based RCT in 160 US students aged 18-24 years comparing tailored advice based on the transtheoretical model of behavior change with non-tailored advice and found no differences in fruit and vegetable consumption [42]. This could suggest that using multiple components in mHealth such as text messaging and coaching calls provide a more personalized approach than Web-based techniques that young adults find helpful for changing their behaviors. The college-based RCT by Gow et al with four treatments including no intervention, 6 weeks of a Web-based intervention, 6 weeks of feedback on weight and calorie intake, and a combination of Web-based intervention with weight and calorie feedback found that the combined group attained the lowest BMI [43]. This further illustrates the advantages of feedback communication in addition to Web resources. Bertz et al studied 167 first-year US college students providing Wi-Fi scales and emailed graphs of weight to show changes compared with no feedback control group. It was found that regular weighing with feedback prevented weight gain [44]. Thus, the importance of building education and counseling with feedback along with ongoing monitoring and self-monitoring into a mHealth program is apparent. The inclusion of a range of demonstrated theory-based behavior change techniques, as in this study, also should be central to any mHealth program [45].

The most successful Web-based intervention to date was conducted in Scotland. Nikolaou et al randomized 20,975 university students to a 40-week three-arm RCT: control and two treatments [46]. While the control group gained weight (mean 2.0 kg, 95% CI 1.5-2.3), both treatment groups lost weight: treatment one −1.0 kg (95% CI −1.3 to −0.5) and treatment two −1.35 kg (95% CI −1.4 to −0.7). Both interventions were novel in their approach. The first treatment was based on the "rational" model that individuals when presented with information will make the best use of it. The messages overtly addressed the problem of weight gain and obesity. The second intervention was by "stealth" and raised discussion around social and political movements associated with food and health and obesity. For 19 weeks, participants would log into the Web-based modules to be completed weekly. The advantage of this study is that it was embedded within the university learning environment and was advertised as a new course being tested. Many undergraduate students participated

after invitation, unlike the other studies that either recruited volunteers from within the college environment or the population at large. While this intervention could likely be adapted for other college students, whether it would be successful when participants must be recruited from the general community of young adults is uncertain.

One of the strengths of this study is that the age range of recruited participants was well distributed between 18 and 35 years. The program reached a greater proportion of males (40%) than usual in weight management studies [10] and included 30% participants who were not born to an English speaking family. However, our results may not be generalizable to all young adults because the study group tended to be of a higher SES and messaging might be country specific.

Limitations

A perceived limitation is that the study maintenance phase was for 6 months only, that is 9 months from baseline, whereas up to 2 years is suggested for weight maintenance [47]. However, maintenance of nutrition behaviors with habit formation may be developed in shorter time frames [48]. Another limitation is the assessment of outcomes using self-report. While there was no difference in the comparison of weight change between both groups when measured and self-reported weight was used at 12 weeks [26], we cannot be certain if this remained the case at 9 months from baseline. The IPAQ may not be sufficiently sensitive to monitor changes in physical activity [28]. Although acknowledged as a limitation, the use of an objective measure like biomarkers is not practical for a remotely delivered intervention and costs of providing Wi-Fi enabled scales, from which data can be accessed, may prove too costly for such an intervention if it is to be scaled up in the population. Recruiting young adults to participate in lifestyle intervention proved challenging in this study. Both the primary care physicians and their patients had a lower than expected uptake of the program [21]. Costs, time, and methods of recruitment require consideration when planning replication trials or scale-up and roll out. Further consideration should be given to recruiting a larger sample size to determine the effects on well-being because, while no evidence was provided in this study, the 95% confidence intervals include beneficial values. Finally, the study had multiple components and we did not attribute the changes to any component in isolation. While the 12-week findings from our study were included in a recent meta-analysis of mobile phone apps for weight loss, it can be seen that less than half the sample downloaded the apps [49].

Conclusion

In conclusion, delivery of an mHealth theory-based intervention for healthy lifestyle and prevention of weight gain in 18- to 35-year-olds was effective in achieving and maintaining weight loss and improved diet behaviors. Countries such as the United States, United Kingdom, and Australia are recognizing that programs with wide reach but of low cost are required in young adulthood [18]. Although the messaging component of the mHealth program was developed in the local context, the behaviors targeted are globally problematic with SSB consumption, high-fat, high-energy take-out meals, and poor vegetable intakes prominent in young adults in the United States [18]. Given the potential for universal adoption and wide reach in this age group, we suggest replication trials of mHealth be conducted in a broader range of young adults throughout countries battling obesity.

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Authors' Contributions

MAF, KM, AB, LH, KB, EDW, MFH designed the trial. MAF, AW, KB, and SRP acquired the data. SRP performed the statistical analysis with input from KM, MAF, and AB. MAF drafted the manuscript with input from SRP. All authors assisted in interpretation of findings and approved the final manuscript content.

Conflicts of Interest

MAF was on the Research Advisory Board of the Australian Primary Health Care Institute. MFH is a director of Central and Eastern Sydney Primary Health Network.

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Original Paper

Optimizing a Text Message Intervention to Reduce Heavy Drinking in Young Adults: Focus Group Findings

Brian Suffoletto[1], MD, MS; Jeffrey Kristan[1], BS; Laurel Person Mecca[2], MA; Tammy Chung[3], PhD; Duncan B Clark[3], MD, PhD

[1]University of Pittsburgh, Department of Emergency Medicine, Pittsburgh, PA, United States

[2]Qualitative Data Analysis Program, University Center for Social and Urban Research, University of Pittsburgh, Pittsburgh, PA, United States

[3]University of Pittsburgh, Department of Psychiatry, Pittsburgh, PA, United States

Corresponding Author:
Brian Suffoletto, MD, MS
University of Pittsburgh
Department of Emergency Medicine
Iroquois Building, Suite 400A
3600 Forbes Avenue
Pittsburgh, PA, 15261
United States
Phone: 1 412 901 6892
Fax: 1 412 647 6999
Email: suffbp@upmc.edu

Abstract

Background: Recent trial results show that an interactive short message service (SMS) text message intervention, Texting to Reduce Alcohol Consumption (TRAC), is effective in reducing heavy drinking in non-treatment-seeking young adults, but may not be optimized.

Objective: To assess the usability of the TRAC intervention among young adults in an effort to optimize future intervention design.

Methods: We conducted five focus groups with 18 young adults, aged 18-25 years, who had a history of heavy drinking and had been randomized to 12 weeks of the TRAC intervention as part of a clinical trial. A trained moderator followed a semistructured interview guide. Focus groups were audiotaped, transcribed, and analyzed to identify themes.

Results: We identified four themes regarding user experiences with the TRAC intervention: (1) ease of use, (2) comfort and confidentiality, (3) increased awareness of drinking behavior, and (4) accountability for drinking behavior. Participants' comments supported the existing features of the TRAC intervention, as well as the addition of other features to increase personalization and continuing engagement with the intervention.

Conclusions: Young adults perceived the TRAC intervention as a useful way to help them reduce heavy drinking on weekends. Components that promote ease of use, ensure confidentiality, increase awareness of alcohol consumption, and increase accountability were seen as important.

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KEYWORDS

alcohol; young adult; text messages; qualitative

Introduction

Heavy episodic drinking, typically defined as consuming four or more drinks for women and five or more drinks for men over a drinking occasion, is the most common pattern of excessive alcohol consumption in the United States [1]. Young adults have an especially high prevalence of heavy episodic drinking [2] and suffer a multitude of related health and social consequences including death and serious injury, primarily from motor vehicle accidents, homicides, and suicides [3]. Research studies have shown that brief counseling interventions can be effective in reducing alcohol consumption and related risks among young adults in various settings [4], but are limited in

their ability to scale up due to costs and training requirements [5].

Computerized interventions may allow for economies of scale and standardization of procedures to ensure replicability that is less feasible with in-person interventions. As well, mobile communication technology allows computerized interventions to provide support over time in an individual's natural environment, and to adapt feedback based on changing personal circumstances [6]. This may be especially useful for interventions targeting substance use [7], which is highly dependent on contextual challenges to self-regulation [8] and requires ongoing self-management [9].

The Texting to Reduce Alcohol Consumption (TRAC) intervention was iteratively developed from a systematic literature review of alcohol prevention interventions and short message service (SMS) text message interventions for health behaviors, and pilot studies [10-13]. Specifically, in 2010, we began developing the TRAC intervention, a computerized intervention using text messaging, to help young adults reduce alcohol consumption. In 2011, we completed a pilot randomized controlled trial (RCT) where we found that young adults used the TRAC intervention at high rates over a 12-week period and that it was potentially useful in helping them reduce heavy drinking [10]. In 2012, we conducted an online crowdsourcing study where young adults—78% with past hazardous drinking—ranked our existing text messages and created new messages they would find useful for reducing alcohol use [11]. In 2013, we used feedback from these prior studies to design an updated TRAC intervention, which is detailed in the Methods section. In 2014, we completed a randomized controlled trial of 765 young adults in which the TRAC intervention produced reductions in heavy drinking days compared to control and assessment-only groups out to 9-month follow-up [12,13]. Despite these findings, we found increasing nonadherence to the TRAC intervention over the 12-week intervention and a significant proportion of participants who continued to exhibit heavy drinking at follow-ups. This suggests a need to continue to improve the intervention's usability, defined as the measure of the ease with which it can be learned and used, including its effectiveness and efficiency [14].

In this study, we address the need to continually improve the intervention through an iterative process of testing and evaluation, by collecting feedback from young adult drinkers who were exposed to the TRAC intervention. This iterative process follows the guiding principles of user-centered design [15] as well as recommendations for development of technology-based behavioral interventions [16]. This study is unique relative to existing literature on the formative development of text message interventions for alcohol use prevention [17-20]. It is unique in that we examine the opinions of individuals who actually experienced an intervention—as opposed to being presented with theoretical or sample messages—and who reflected on how the intervention's various features impacted their thoughts, beliefs, and behaviors.

Methods

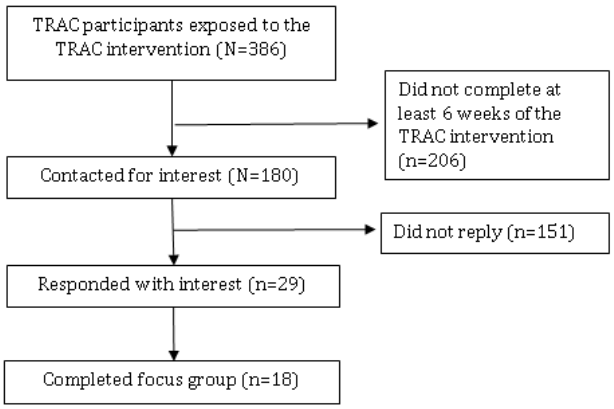
Study Design

The specific aim of this study was to understand young adults' qualitative experiences using the TRAC intervention and explore ways to improve its usability. Five focus groups, each consisting of 3-5 people, were conducted. We probed user reactions to the TRAC intervention in general as well as specific TRAC intervention components, including drinking assessments, goal-setting prompts, and feedback messages. Finally, we gauged participant opinions about candidate additions to the TRAC intervention and probed for any other suggested changes. All participants provided written informed consent. Study procedures were approved by the Institutional Review Board at the University of Pittsburgh. None of the findings reported in this manuscript have been described in prior publications.

Recruitment and Participants

We recruited focus group participants from those who met eligibility criteria for the TRAC trial (ClinicalTrials.gov number: NCT 01688245). TRAC participants were identified in four emergency departments (EDs) in Pittsburgh, Pennsylvania. TRAC trial inclusion criteria were as follows: 18-25 years of age, having screened positive for past hazardous alcohol consumption—Alcohol Use Disorders Identification Test Consumption (AUDIT-C) score >3 for women and >4 for men [21]—and not seeking help for their alcohol use. Inclusion for this focus group study also required randomization to the TRAC intervention condition (n=386). We limited focus group enrollment to those individuals who had completed at least 6 weeks (50%) of the SMS text messaging assessments so that participants would be able to reflect on actual experiences using the TRAC intervention. Invitations were sent via email to 180 individuals and we received preliminary interest from 29 (16.1%). For each session, we attempted to invite an equal number of women and men as well as at least one person who had self-identified as black. In total, 18 individuals took part in the focus group study. The flow diagram of focus group participants can be seen in Figure 1.

Figure 1. Flow diagram of focus group participants. TRAC: Texting to Reduce Alcohol Consumption.



The Texting to Reduce Alcohol Consumption Intervention

The overall goal of the TRAC intervention is to help young adults reduce their alcohol consumption. TRAC targets heavy episodic drinking, given its association with alcohol-related harms [3], and in particular, heavy episodic drinking on weekends because that is when most binge drinking occurs among young adults [22]. The design was chiefly informed by the theory of planned behavior [23] and goal-setting theory [24], incorporating self-monitoring, goal-commitment prompts, and immediate tailored feedback messages, all of which have been shown to be effective components of mobile behavioral interventions for reducing alcohol consumption [25]. The TRAC intervention was designed to function for individuals with a variety of levels of readiness to change, to accommodate shifting motivations from week to week, and to offer an action plan to anyone reporting likelihood of having a heavy drinking episode over the weekend. It was programmed to run for 12 weeks, a period that would provide time for individuals to learn to adopt safer drinking habits without repetition of the intervention. All content and user flow of the TRAC intervention was developed primarily by the first author (BS) in consultation with an adolescent addiction psychiatrist (DBC) and computer programmer. The program was run from servers and a modem pool housed at the university.

Upon enrollment to the TRAC intervention, participants received a series of welcome messages instructing them on what to expect over the 12 weeks and how to quit the program. The flow of text message branching logic can be seen in Multimedia Appendix 1 and a full description of the TRAC intervention with sample message libraries can be found in prior publications [12]. In brief, each Thursday at 6pm, participants were asked to report if they planned on drinking that weekend, and if they responded in the negative (ie, “no,” “nah,” or “N”), they received a message reinforcing their choice not to drink. If they responded that they planned on drinking (ie, “yes,” “yup,” or “Y”), they were asked whether they were likely to drink five or more drinks (for men) or four or more drinks (for women) on any occasion over the weekend. If they responded that they were not likely to have a heavy drinking episode over the weekend, they received a message encouraging their choice and another informing them about safe drinking. If they responded that they were likely to have a heavy drinking episode, they were asked whether they were willing to set a goal to limit their drinking to below the heavy drinking threshold—five or more drinks for men/four or more drinks for women— that weekend. If they responded that they were not willing to set a goal to limit their drinking, they received a message expressing understanding of the difficulty in making changes. If they responded that they were willing to set a goal to limit their drinking, they received a message encouraging that goal and another message encouraging use of a specific protective behavioral strategy.

Each Sunday at 12pm, participants were asked to report the most alcoholic drinks they had consumed on any single occasion between Thursday and Sunday. If they reported that they did not drink (ie, “none,” “zero,” or “0”), they received a message congratulating them for not drinking. If they reported a value greater than zero, but less than the heavy drinking threshold, they received a message acknowledging their report of drinking and another message with general alcohol education. If they reported drinking above the heavy drinking threshold, they received a message expressing concern and another message prompting them to reconsider their drinking behavior. All feedback messages were modeled on existing language used in brief interventions for alcohol use and in the spirit of motivational interviewing.

Focus Groups

We chose to conduct focus groups for several reasons. First, focus groups are a fast and efficient method for obtaining data from multiple participants [26]. Second, focus groups can increase participants’ sense of belonging [27] and help them to feel safe, facilitating sharing of information [28]. This may be particularly relevant to sensitive topics such as alcohol use [29]. Third, focus groups can stimulate conversations around ideas or themes, yielding important data not elicited in one-on-one interviews [30].

Before conducting any focus groups, a standardized, semistructured qualitative guide was developed to increase consistency across interview sessions. We pilot-tested the interview guide among 3 young adult volunteers—2 female and 1 male— not previously exposed to the TRAC intervention and

made refinements based on their feedback. The guide probed user reactions to the TRAC intervention in general as well as to the three main features of the TRAC intervention: drinking plan and consumption queries, goal-setting prompts, and feedback messages. The interview guide also probed opinions about possible additions to the TRAC intervention. Specifically, we were interested in understanding how young adults felt about incorporating text messaging during drinking episodes because of prior trial findings that a significant proportion of young adults who set drinking limit goals still did not meet them, and our belief that messages delivered more proximal to actual drinking events could enhance potency. We also probed opinions about a Web-based dashboard as an adjunct to text messaging given prior expressed desire among young adult participants for an easier way to track their progress over time.

Each focus group was scheduled to comprise small groups—3-4 individuals—to ensure participant interaction and comfort [31]. Each focus group lasted about 90 minutes and was conducted in a private university conference room in the evening. The focus groups were conducted by a female facilitator (LPM) with expertise in focus group techniques and qualitative methodology.

Before each focus group began, participants provided written informed consent. The consent highlighted the potentially sensitive nature of the discussions and urged participants to not share discussion content outside the group. As well, at the beginning of each focus group, the moderator stressed the confidential nature of the discussion to the participants. Participants were told that the focus group discussion would be audiotaped, would be used for research purposes only, and would not be accessible to anyone outside the research team. To ensure confidentiality, participants were told not to use their full names. It was stressed that the opinions of the participants were important and that there were no right or wrong answers.

The focus groups started with a warm-up where participants were reminded of the TRAC intervention format. Probes were used to encourage clarification and evoke greater detail from participants' narratives. A research assistant took detailed field notes during the focus groups and the groups were audiotaped and transcribed by personnel at the Qualitative Data Analysis Program at the University Center for Social and Urban Research at the University of Pittsburgh. At the conclusion of each focus group, we debriefed all participants on the preliminary results of the randomized trial and asked for any closing remarks or questions. When all participants' questions had been exhaustively answered, the participants were thanked and provided with a debit card worth US $30.

Data Analysis

We chose a thematic content analysis approach and used the qualitative research software package, ATLAS.ti 5.0 (Scientific Software Development). A preliminary codebook was created based on close readings of the first transcripts, incorporating explicit domains from interview guides (deductive themes) as well as recurrent unanticipated themes that were emergent across transcripts (inductive themes). Provisional definitions were given to each code and two analysts applied the codes to each transcript. The coded transcripts were merged for comparison and code definitions were revised based on an examination of coding disagreement. Coded text was further reviewed through an iterative process, resulting in refined themes. We did not record which individual participant said which statement or count how many participants agreed or disagreed with a given statement. In presenting the results, we chose participant quotes that represented both the majority sentiments within each theme as well as any quote that offered a contrasting opinion within that theme.

Results

Overview

We conducted five focus groups with 18 participants—12 females (67%) and 6 males (33%). Overall, the sample was 44% (8/18) non-Hispanic black and 50% (9/18) non-college educated; 28% (5/18) were under the US legal age of 21 years to purchase or consume alcohol. There was a high rate of cannabis use (11/18, 61%) and daily tobacco use (7/18, 39%) among our cohort. Other baseline characteristics of focus group participants can be seen in Table 1. During the trial, focus group participants responded to an average of 97% of Thursday text message queries and 95% of Sunday text message queries.

Table 1. Baseline characteristics of focus group participants (n=18).

Characteristics		Mean (SD) or n (%)
Age in years, mean (SD)		22 (2)
Underage (<21 years), n (%)		5 (28)
Female, n (%)		12 (67)
Race, n (%)		
	Black	8 (44)
	White	10 (56)
	Other	0 (0)
	Hispanic	0 (0)
College educated, n (%)		9 (50)
Employment, n (%)		
	Not working	5 (28)
	Part time	5 (28)
	Full time	8 (44)
Other substance use (past 3 months), n (%)		
	Tobacco, daily or almost daily	7 (39)
	Any cannabis	11 (61)
AUDIT-C[a] score, mean (SD)		7 (2)

[a]AUDIT-C: Alcohol Use Disorders Identification Test Consumption.

Overall Themes

Analysis revealed the following four major themes regarding experience with the TRAC intervention: (1) ease of use, (2) comfort and confidentiality, (3) increased awareness of drinking behavior, and (4) accountability for drinking behavior.

Theme One: Ease of Use

Participants expressed that text messaging was an ideal electronic modality to deliver drinking support. They naturally contrasted text messaging with other electronic modalities. For example, one participant explained, “I remember thinking it was a great method because it’s—you can respond to it very quickly, it’s not like you have to log into a computer.” Another said, “It’s convenient, especially for us for our generation, I think more so than being on the computer, you know, checking our emails.” Another described, “It’s way better than the app because it hits you. You know, it’s a text message right straight to your phone.” One participant did however comment that text messaging is easy to use but may not be the most impactful modality given that it is limited to text and 160 characters: “Even though it is very accessible, I don’t know if it’s the most, you know, high impact way to reach somebody.”

Theme Two: Comfort and Confidentiality

Overall, participants seemed to feel comfortable texting about their drinking behaviors. In fact, they described how the text messaging modality was preferred to in-person disclosure of drinking, with a resultant feeling of not being judged. For example, one participant said, “I thought it was more comfortable just because when you’re in front of somebody and you’re like, ‘Oh, I had 20 drinks.’ Some people are kind of like, ‘20 drinks?! That’s a lot.’” Regarding confidentiality, one participant said, “I felt like nobody was going to see it. I know someone was going to see it but it was like, it was on [my] phone, it’s gone, I don’t have to worry about it again, you know? And if I don’t want anyone to look at my phone and see that, then I just delete it.” Some participants did express some concerns about confidentiality, but that it became less of a concern as the intervention continued. One participant summed up his evolving feelings this way: “I thought it was kind of funny at first just like I’m texting this nobody, I didn’t know if it was real or something...but it just became routine...and then I was like, ‘You know what? I’m being honest now.’”

Theme Three: Awareness of Drinking Behavior

Participants indicated that they were not very aware of the extent of their drinking prior to starting the TRAC intervention. For example, one participant said, “I really went into it thinking like, ‘I’m not really going to need this because I don’t drink too much.’” Many recalled that the repetitive nature of the week-to-week drinking assessments helped them develop a habit of paying attention to how much they drank. For example, one participant said, “The consistency keeps reminding you...then you started to think, ‘Well, am I drinking this much this weekend?’” Several participants commented on how it is difficult to estimate drinking quantity in the real world. For example, one participant said, “You know, I might have had four red solo cup glasses, but you know there could have been two shots in there, could have been three shots in there.”

Participants commented that the feedback messages on Sunday, after reporting weekend drinking quantity, made them more aware of their drinking, but individuals seemed to have differing opinions on which types of feedback messages were preferred. Some participants liked the statistics on the dangers of heavy drinking: "Any time I get statistics, they obviously like stick in people's heads with cigarette smoking, drinking, STD, like anything. So, I love the statistics." Others felt that the messages were not telling them anything they did not already know. For example, one said, "I remember thinking, '[pfft] okay, whatever.' And even with the [protective behavioral] strategies, I think we know what we're supposed to be doing."

Many discussed how the TRAC intervention helped them become aware of the drinking habits of their peers. For example, one participant commented, "When I go to parties or I see people drinking, I'm just like, 'Do you know how many drinks you're consuming?' Like I count people's drinks for them...and I'm like, 'Why are you doing that to yourself?'" Another participant commented about how the intervention influenced their peer group: "It helped my friends too because they'd see me doing [TRAC] and they'd be like, 'Oh, maybe we shouldn't have like 12 shots before we go out.'"

Theme Four: Accountability for Drinking Behavior

Overall, participants seemed to feel that the TRAC intervention made them feel more accountable for their drinking choices. One participant illustrated this point in saying, "The fact that it's constantly in your face and you get a chance to see how much you drink and how often it is, makes you—makes your mind wonder. And it helps you to kind of be able to control it [your drinking], if you want to." Participants felt that the one feature that seemed to bring about the feeling of accountability was the goal-commitment query sent each Thursday, commenting that it made them be more mindful when they were out drinking. For example, one participant said, "...I thought about it [the goal] when I don't think I normally would have. So, even if I didn't reach it [low-drinking-quantity goal], I was at least thinking about the amount I was drinking, which was a positive." Another TRAC intervention feature that seemed to bring about the feeling of accountability was the alcohol consumption recall query sent each Sunday. One participant recalled, "I'd wake up, you know, ridiculously hungover day after day and I'd start to see these messages. I'm like, 'Alright, well I should kind of like tone it back.'"

Some participants expressed some discomfort with the feeling of being held accountable. For example, one participant said, "It's like your mom telling you, 'What the heck are you doing?' but in a text. But it made you think about it, and sometimes, yeah, it was uncomfortable, but if you're honest about it, then it's gonna help you recognize you have a problem." Some mentioned that the feeling of being accountable for their drinking lasted beyond the intervention period. For example, "I still count. Like I still—I don't have a calendar but I keep track, which I never did because I never thought about it."

Suggestions for Improvement of the Texting to Reduce Alcohol Consumption Intervention

Discussion revealed areas for improvement. For example, some participants reported intervention fatigue; one participant stated, "Sometimes I would answer honestly, but if I didn't really feel like all the texting, I would just be like, 'I followed the goal, followed through with my goal' just so I wouldn't have to keep going." However, at least one participant suggested providing the option of continuing the program for longer than 12 weeks, if desired.

Participants had noteworthy suggestions for reducing intervention fatigue and improving engagement with the TRAC intervention. In general, participants supported the use of more personalization by sending messages using their first names. Participants also suggested incorporating more tailored feedback. For example, one participant said, "Maybe if you could identify the factor or reason why they were trying to quit, so like saving money and you factor that into the messages." Regarding tailoring of the goal-commitment query, participants suggested using drinking quantity thresholds higher than the four or five drinks per occasion recommended by the National Institute on Alcohol Abuse and Alcoholism (NIAAA). One participant commented that the recommended maximum drinking quantities during Thursday goal-setting prompts were "pretty much nothing"—that is, they were too low to experience an effect from drinking.

When we probed the possibility of incorporating text messages to support low-quantity drinking goals during drinking episodes, participants were ambivalent. For example, one participant stated, "I mean everybody is on their phone when they're drinking, but I think that some other people might get offended or might get annoyed, irritated. But I think for me, that would be beneficial, just as kind of a reminder in the back of your head, 'Hey, just reminding you, be mindful of how much you're drinking.'" A participant suggested that one-way "push" messages, which provided a reminder of the goal to limit drinking, could help to optimize the effect of goal setting while minimizing participant burden.

When we probed the possibility of incorporating a Web-based dashboard where their text message data could be stored and graphically displayed, participants were generally supportive. One suggested addition was the ability to compare progress to others. For example, one participant said, "I like to see things quantified and it would actually be interesting, like same age, peers. This is their trend." It was suggested that the dashboard also incorporate some form of gamification. For example, one participant said, "I could see a lot of value in some sort of a reward scheme." Additionally, it was suggested that there be a social network component. One participant illustrated how this would be helpful: "If you just had maybe like a website that, you know, just had...other people's stories and experiences. Like I don't know how many people would be like, 'Oh my gosh, my weekend was terrible, anybody else feel the same way?'"

Discussion

Principal Findings

This focus group study summarizes the opinions of non-treatment-seeking young adults with past hazardous alcohol consumption who were exposed to an interactive 12-week text message intervention focused on reducing weekend heavy drinking episodes. Participants recalled positive experiences with the TRAC intervention, citing ease of use and immediacy in the natural context of life as major facilitators in reducing alcohol use. Participants recounted how the intervention made them more aware about their own drinking patterns and felt it prompted accountability to drink more moderately. Although each intervention piece, namely the weekend drinking plan query, the goal-commitment prompt, and the Sunday alcohol consumption check-in, seemed to play unique roles, the intervention pieces also seemed to function together synergistically. Moreover, the repetition from week to week seemed to help individuals build alliance with the intervention over time and support reduction in drinking behavior.

Participant comments regarding the ease of use is not surprising given that text messaging is ubiquitous on mobile phones, a common mode of communication among young adult drinkers, and combines immediacy with the ability to reply asynchronously [32]. Participant overall comfort with communicating about drinking and feelings of adequate confidentiality may be surprising to some given that text messaging is considered an "unsecure" communication modality. However, research suggests that communication about sensitive topics such as alcohol and other substance use may actually be preferred through electronic modalities [33].

The TRAC intervention seemed to help individuals learn how to track the amount of alcohol they consumed. Although the act of assisting self-monitoring of drinking through Sunday alcohol consumption check-ins may be an important mechanism of action, it is clearly not the only necessary element. For example, in our trial findings, the assessment-only control group, which received Sunday alcohol consumption check-ins but did not receive feedback, showed no reductions in alcohol consumption at follow-ups [13]. One possible explanation is that self-monitoring of drinking quantity alone, without feedback, is not enough to change behavior among young adult drinkers, as has been found in other studies of alcohol use [34]. Another possible explanation may be that *awareness* of alcohol consumption occurs as a result of other intervention components (eg, goal-commitment prompts) or the components acting together as a whole.

The TRAC intervention elicited feelings of accountability in some individuals, which seemed to stem from developing a discrepancy between their perception of their drinking and what they had *learned* about their drinking behavior over the course of the intervention. It also seemed to stem from their growing awareness of the hazardous drinking patterns of their peer groups. We speculate that these perceived discrepancies motivated many to change their drinking over the course of intervention exposure and fits with one of the main theoretical underpinnings of the TRAC intervention, the theory of planned behavior, which stresses the importance of goal setting and perceived norms regarding alcohol use on alcohol consumption [35]. We also noted that what began as feelings of accountability to the TRAC intervention appeared to shift to feelings of accountability to themselves over the course of intervention exposure. This suggests that accountability for limiting drinking may become internalized through repetition over the course of the intervention for some young adults.

There were a number of design improvements that participants suggested, including increasing personalization and tailoring, such as adding the first name to texts and providing the option to continue the intervention for longer periods. Some participants seemed to desire more adaptive goal-commitment prompts. Specifically, some felt that limiting themselves to four or five drinks was too low of a threshold to commit to, especially when they are used to drinking 10 or more drinks on a weekend evening. This notion was reflected in our trial, where we found that young adults were not willing to commit to a drinking limit goal around half the time. It also raises an interesting dilemma for operationalizing design, where we would essentially ask young adults to commit to drinking less than what they are used to but higher than four or five drinks, the current upper limit of what the NIAAA considers a moderate level of alcohol use. Participants were ambivalent about receiving support messages during weekend drinking occasions, and stressed that, if they are used, they should be one way (ie, not interactive) to minimize burden and should focus on reminding individuals about their goals, only if they set one. Finally, participants were generally supportive of a Web-based dashboard incorporating features such as graphical feedback, gamification, social networking. This is not surprising given the recent growth in commercial programs to track health that utilize these online features.

Our findings complement existing literature describing formative research on how to design text message interventions for hazardous alcohol use prevention. For example, Sharpe et al [17] found that 18-60-year-olds with past hazardous alcohol use wanted text message content that was engaging, relevant, and useful for recipients, including reducing the complexity of message content and structure, increasing the interactivity, ensuring an empowering tone to text messages, and optimizing the appropriateness and relevance of text messages. Bock et al [18] found that community college students wanted messages that apply to specific drinking contexts, including messages for before and after a drinking occasion and messages that are tailored to different drinking habits (ie, age and drinking experience). In other work, Muench et al [19,20] found that individuals in addictions treatment programs tended to prefer benefit-driven over consequence-driven messages, and messages that are tailored to commonly encountered hypothetical situations. Our study is the first to have individuals comment on how they actually experienced the text message intervention in the real world and reflect on how the various features potentially impacted their thoughts, beliefs, and behaviors.

Limitations

Findings may not be applicable to other populations, such as young adults with less severe alcohol use, or other age groups,

such as adolescents. This is especially relevant given the high rates of comorbid tobacco and marijuana use in our cohort. We only recruited participants in the TRAC intervention arm who had completed at least 6 weeks (50%) of the SMS text messaging assessments, which could have resulted in undersampling the opinions of those who dropped out. Focus groups were conducted at least 6 months after completion of the TRAC intervention, and therefore recall of real-time perceptions might be influenced by memory biases. Finally, the users' opinions were based on their experiences with one intervention design, and may not be the same with different text message alcohol intervention designs.

Conclusions

Young adults perceived the TRAC intervention as a useful way to help them reduce heavy drinking on weekends. Important themes regarding usability of the TRAC intervention included its ease of use, confidentiality, and its ability to increase personal awareness of alcohol consumption and accountability for personal drinking behavior. Focus group discussion indicated that text message interventions should attempt to personalize materials based on user-specific features, such as drinking severity, and provide additional support through online adjuncts.

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Conflicts of Interest

BS has a financial conflict of interest; he has a copyrighted mobile text message system which is licensed to healthStratica, for which he has received royalties.

Multimedia Appendix 1

The flow of text message branching logic for the Texting to Reduce Alcohol Consumption (TRAC) intervention.

[PNG File, 233KB - mhealth_v4i2e73_app1.png]

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Abbreviations

AUDIT-C: Alcohol Use Disorders Identification Test Consumption
ED: emergency department
NIAAA: National Institute on Alcohol Abuse and Alcoholism
RCT: randomized controlled trial
SMS: short message service
TRAC: Texting to Reduce Alcohol Consumption

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Original Paper

Remotely Delivered Exercise-Based Cardiac Rehabilitation: Design and Content Development of a Novel mHealth Platform

Jonathan C Rawstorn[1,2]; Nicholas Gant[2], PhD; Andrew Meads[3], PhD; Ian Warren[3], PhD; Ralph Maddison[1], PhD

[1]National Institute for Health Innovation, University of Auckland, Auckland, New Zealand

[2]Department of Exercise Sciences, University of Auckland, Auckland, New Zealand

[3]Department of Computer Science, University of Auckland, Auckland, New Zealand

Corresponding Author:
Jonathan C Rawstorn
National Institute for Health Innovation
University of Auckland
Private Bag 92019
Auckland Mail Centre
Auckland, 1142
New Zealand
Phone: 64 9 373 7599 ext 84498
Fax: 64 9 373 1710
Email: j.rawstorn@auckland.ac.nz

Abstract

Background: Participation in traditional center-based cardiac rehabilitation exercise programs (exCR) is limited by accessibility barriers. Mobile health (mHealth) technologies can overcome these barriers while preserving critical attributes of center-based exCR monitoring and coaching, but these opportunities have not yet been capitalized on.

Objective: We aimed to design and develop an evidence- and theory-based mHealth platform for remote delivery of exCR to any geographical location.

Methods: An iterative process was used to design and develop an evidence- and theory-based mHealth platform (REMOTE-CR) that provides real-time remote exercise monitoring and coaching, behavior change education, and social support.

Results: The REMOTE-CR platform comprises a commercially available smartphone and wearable sensor, custom smartphone and Web-based applications (apps), and a custom middleware. The platform allows exCR specialists to monitor patients' exercise and provide individualized coaching in real-time, from almost any location, and provide behavior change education and social support. Intervention content incorporates Social Cognitive Theory, Self-determination Theory, and a taxonomy of behavior change techniques. Exercise components are based on guidelines for clinical exercise prescription.

Conclusions: The REMOTE-CR platform extends the capabilities of previous telehealth exCR platforms and narrows the gap between existing center- and home-based exCR services. REMOTE-CR can complement center-based exCR by providing an alternative option for patients whose needs are not being met. Remotely monitored exCR may be more cost-effective than establishing additional center-based programs. The effectiveness and acceptability of REMOTE-CR are now being evaluated in a noninferiority randomized controlled trial.

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KEYWORDS

telemedicine; telerehabilitation; wireless technology; remote sensing technology; behavioral medicine; myocardial ischemia

Introduction

Coronary heart disease (CHD) is a leading cause of mortality and morbidity worldwide. CHD accounts for 1 in 7 deaths in the United States, approximately 1 in 20 adults have diagnosed CHD, and its prevalence is expected to increase ≈18% by 2030 [1]. Furthermore, people with CHD account for more than 40% of all CHD events, more than 35% of nonfatal myocardial infarction, and more than 50% of fatal coronary events [2]. This emphasizes the need for effective secondary prevention programs that target modifiable cardiovascular risk factors in order to reduce the risk of recurrent cardiac events and mortality.

Cardiac rehabilitation (CR) is an essential component of contemporary cardiac care, and exercise training is consistently identified as a central element in international guidelines [3-5]. Exercise-based cardiac rehabilitation (exCR) is commonly delivered in hospitals and rehabilitation clinics (center-based exCR) and should include an individualized, progressive program of aerobic and strength training that accounts for patients' clinical status, risk stratification, comorbidities, and goals [4]. ExCR improves all-cause and cardiac mortality, recurrent cardiac event risk, several modifiable cardiovascular risk factors, and exercise capacity [5-10], and is more cost-effective for reducing premature death than most common pharmacological and surgical interventions [11]. However, referral rates and uptake of exCR are low [11-13], and participation is commonly limited by program availability, transport restrictions, inconvenient program scheduling, and domestic or occupational responsibilities [14,15]. These barriers suggest accessibility is a primary factor limiting utilization of traditional center-based exCR programs, and overcoming participation barriers should be prioritized, as nonattendance is associated with poorer risk factor knowledge and risk profile [16].

Home-based exCR programs enhance accessibility [17] and provide comparable health benefits [18], but cannot deliver the supervision, feedback, and individualized coaching provided by exCR specialists during center-based exCR. These limitations preclude optimal individualization of exercise prescription and may limit improvements in modifiable cardiovascular risk factors and functional capacity [19,20].

Information and communication technologies offer opportunities to augment home-based exCR by connecting exCR specialists with patients outside the clinical environment. Telehealth-assisted programs have commonly used fixed-line telephones, email, and mobile phone short message service (SMS) to deliver motivational support, behavioral change counseling, and feedback about goal achievement or exercise adherence [21-31]. Additional telehealth interaction between patients and exCR specialists augments early home-based exCR programs, and secondary prevention effects appear promising. However, constraints of commonly used telehealth technologies have limited program flexibility and are unable to emulate the exercise supervision, coaching, and individualization, which are typical of center-based exCR. Some telehealth exCR platforms have enabled patients to upload accelerometer or heart rate data to Web-based portals to be reviewed by exCR specialists [22,24-26,30,31]. However, asynchronous uploading of data has limited the utility of these platforms to high-level review of physical activity and adherence.

Telehealth exCR has, to date, been unable to provide exercise monitoring, feedback, coaching, and individualized exercise prescription in a manner consistent with best practice international CR guidelines; however, rapid advances in mobile sensor and communication technologies can help bridge this gap. Increasingly powerful smartphones, rapid mobile broadband connection speeds, and interoperable wearable sensors mean the technological capability for real-time remote exercise monitoring and coaching is now readily available. Smartphones are appealing for health intervention delivery as they enable individualized and timely provision of intervention content [12]. Moreover, rapid growth in smartphone mobile phone ownership (≈75% in many countries), mobile broadband subscriptions (80% in developed countries), and coverage (70% and 90% of the total and urban global population, respectively) [32-34] suggest the time is right to introduce more sophisticated telehealth exCR platforms that can optimize program flexibility, accessibility, responsiveness, and individualization. This is supported by results from several studies that indicate telehealth exCR has beneficial effects on modifiable cardiovascular risk factors [21-31], but intervention characteristics are likely constrained by telehealth platforms that do not enable sufficient individualization of exercise prescription or monitoring of exercise performance [27]. Furthermore, predominant reliance on fixed-line telephone communications in previous telehealth exCR interventions constrains patients within the home environment and limits program flexibility.

The feasibility of more advanced mobile health (mHealth) exCR platforms comprising wearable sensors, smartphones and real-time remote data transmission has been demonstrated [15,35], but only one evaluation study has been published.

Real-time remotely monitored exercise improves submaximal aerobic exercise capacity and health-related quality of life (HRQoL) for patients undergoing percutaneous coronary intervention; [26] however, real-time monitoring was only sustained for 2 weeks and it was unclear whether exCR specialists used the data to inform real-time individualized feedback or coaching. One of these platforms (REMOTE-CR) is currently being evaluated in a noninferiority randomized controlled trial comparing mHealth and center-based exCR [36].

Embracing advances in wearable sensor and mobile communication technologies can enable mHealth exCR to combine the universal accessibility of home-based exCR with the clinical expertise, supervision, and coaching that has traditionally been limited to center-based exCR. These opportunities have yet to be capitalized on and addressing them could substantially increase the reach of exCR by providing more flexible, responsive, and interactive alternatives to existing center- and home-based programs. This article describes the development of an mHealth exCR platform designed to address these limitations. The paper first defines the main platform design objectives and then describes how components of an mHealth CR development framework were integrated into the design process. Subsequent sections outline the platform design, including the technology components and intervention content development.

Methods

Design Objectives

The primary purpose of the mHealth exCR platform was to overcome accessibility barriers that limit center-based exCR participation while retaining the clinical expertise provided by exCR specialists during center-based programs. The major platform design objectives were to provide universal access to real-time exercise monitoring, coaching, and feedback and theory-based behavior change strategies. To achieve these

objectives, we aimed to develop an alternative for the large number of CHD patients whose needs are not currently being fulfilled by center-based exCR programs.

We developed an mHealth exCR platform, named REMOTE-CR, that integrates smartphones, wearable sensors, and custom smartphone and Web-based apps to provide real-time remote exercise monitoring, evidence-based exercise prescription and coaching, theory-based behavior change education, and social support to CHD outpatients in almost any location. REMOTE-CR was designed to optimize ease of use and allow rapid scalability while adhering to evidence-based guidelines, as these characteristics will likely facilitate transition into practice [37].

Development Framework

A recently proposed mHealth CR development and evaluation framework suggests CR interventions should address the core components of CR, apply behavior change theory, enable individual tailoring of features, demonstrate high usability, and be evaluated in a randomized controlled trial that assesses patient-centered outcomes [38]. The design, development, and subsequent evaluation of REMOTE-CR were based on this framework, with appropriate adaptations to suit the intended design objectives.

Core Components of Cardiac Rehabilitation

The core components of CR include patient evaluation, medical and lifestyle risk factor management, cardioprotective therapies, psychosocial management, exercise training, and health behavior change education [4,39]. Many traditional center-based exCR programs focus on exercise training and physical activity counseling, while other core components may be delivered via alternative channels such as outpatient clinics and group seminars. As REMOTE-CR is intended to provide an alternative to traditional center-based exCR programs, the platform features also focus on exercise training and physical activity behavior change. We aligned REMOTE-CR with the format of center-based exCR to increase the likelihood of transition into practice, an approach that has previously been recommended for the development of health behavior change interventions [37]. Although REMOTE-CR does not currently include additional core CR components, the platform architecture was designed to enable modular expansion in future iterations. The initial focus on exercise training and physical activity behavior change was intended to facilitate robust evaluation of remotely delivered exCR in comparison with center-based programs.

Behavior Change Theory

Theory-based interventions are considered more effective than those without theoretical underpinning, and integrating principles from behavior change theories into mHealth intervention design may significantly increase the likelihood of success [40,41]. Development of the REMOTE-CR platform and intervention content were informed by behavior change theories including Social Cognitive Theory and its key component self-efficacy [42], Self-determination Theory [43,44], and a taxonomy of behavior change techniques [45].

Self-efficacy refers to individuals' perceptions that they can control their health behaviors [46]; higher levels of self-efficacy are expected to facilitate behaviors that help to maintain self-regulated motivation such as setting goals, creating incentives, and seeking social support [47]. Sources of self-efficacy information include performance accomplishment, vicarious experience, verbal persuasion, and physiological cues. Self-efficacy influences exercise initiation and maintenance [48,49], physical activity level [50], and clinical outcomes [51], is one of the most commonly examined psychological variables in the cardiac setting, and is a recommended intervention component in New Zealand CR guidelines [20].

Self-determination Theory proposes motivational orientation lies on a continuum anchored by intrinsic and extrinsic motivation, where an individual's orientation is determined by effects of environmental and individual factors on the satisfaction of three basic psychological needs: autonomy, competence, and relatedness [43,44,52]. Briefly, intrinsic motivation refers to the pursuit of internal outcomes such as accomplishment, development, and satisfaction; conversely, extrinsic motivation refers to the pursuit of external outcomes such as tangible or social rewards [52]. Autonomy refers to a sense of regulating one's own behavior, competence refers to a sense one's actions, and relatedness refers to a sense of connection with others in a specific setting [43,44]. Competence shares fundamental similarities with self-efficacy as both constructs reference perceived confidence in task-specific success and are informed by performance accomplishment. Perceptions of autonomy, competence, and relatedness are influenced by physical and social environmental factors, individuals' motives for undertaking exercise, and their propensity to pursue intrinsic or extrinsic directives [52]. A comprehensive meta-analysis examining the influence of self-determination on exercise behavior associated more self-determined motivational orientations with superior exercise adoption and long-term adherence [52]. Furthermore, some evidence suggests self-determined motivation has a greater effect on exercise adherence than self-efficacy [49].

While Social Cognitive Theory and Self-determination Theory serve as the theoretical constructs underlying design and development of REMOTE-CR, they do not provide tangible or identifiable intervention components, per se. A taxonomy of behavior change techniques has been developed to identify, define, and categorize active intervention components that are designed to alter processes underlying behavior regulation [45]. The taxonomy defines 93 behavior change techniques across 16 categories. Behavior change techniques that support REMOTE-CR's underlying theoretical constructs (ie, self-efficacy and self-determination) were adapted as required to suit the technological requirements of the REMOTE-CR platform. In total, REMOTE-CR includes 24 behavior change techniques from 10 categories (Table 1). Behavior change techniques were integrated throughout the REMOTE-CR platform, including the intervention content and features of the patient-facing smartphone app and exCR specialist-facing Web-based app.

Table 1. REMOTE-CR behavior change techniques[a].

	Category	Behavior change technique
1	Goals and planning	
	1.1[b,c]	Goal setting (behavior)
	1.2[d]	Problem solving
	1.3[a]	Goal setting (outcome)
	1.4[b,d]	Action planning
	1.5[b,c,d]	Review behavior goal(s)
	1.6[b,c]	Discrepancy between current behavior and goal
2	Feedback and monitoring	
	2.1[b,c]	Monitoring of behavior by others without feedback
	2.2[b,c]	Feedback on behavior
	2.3[b]	Self-monitoring of behavior
	2.4[b,d]	Self-monitoring of outcome(s) of behavior
	2.6[b]	Biofeedback
3	Social support	
	3.1[b,c,d]	Social support (unspecified)
	3.3[b,c,d]	Social support (emotional)
4	Shaping knowledge	
	4.1[c,d]	Instruction on a behavioral act
5	Natural consequences	
	5.1[c,d]	Information about health consequences
8	Repetition and substitution	
	8.1[b]	Behavioral practice/rehearsal
	8.6[d]	Generalization of a target behavior
	8.7[c]	Graded tasks
9	Comparison of outcomes	
	9.1[c,d]	Credible source
10	Reward and threat	
	10.4[c]	Social reward
	10.9[d]	Self-reward
13	Identity	
	13.2[d]	Framing/reframing
15	Self-belief	
	15.1[c]	Verbal persuasion about capability
	15.3[d]	Focus on past success

[a]Behavior change techniques defined by Michie et al [45].

[b]Patient-facing mobile phone app.

[c]exCR specialist-facing Web-based app.

[d]Behavior change education content.

Individualization and Usability

A review of mHealth behavior change suggests individualized interventions are more effective at changing behavior, although few interventions have implemented tailored components [53]. The accessibility of mobile platforms may encourage greater use of tailored features by patients [38], and the REMOTE-CR was designed to include several individualized components including exercise prescription, exercise performance feedback, exercise coaching, goal setting and achievement feedback, and social support. Further details about platform features are discussed in the following section.

CHD patients are mostly of older age; therefore, use of smartphones and wearable sensors presents substantial usability challenges that may affect adoption and adherence. Factors that facilitate mHealth exCR usability are not well defined [38]; however, features such as automated and/or wireless data entry promote ease of use [54]. REMOTE-CR features were designed to minimize the required user input in order to aid usability. The smartphone app was designed with a simple, intuitive user interface and navigational complexity was minimized. Most functions are automated, including tasks such as connecting the smartphone and wearable sensor, recording exercise data, and presenting goal achievement feedback. Furthermore, a custom middleware platform was implemented to manage low-level functions such as authentication, encryption, and connectivity. Appropriate training is also likely to alleviate usability challenges [55]. A face-to-face training module was developed to explain REMOTE-CR platform functionality. The module includes verbal instruction, demonstration, and hands on practice. The training module is supported by an illustrated user guide that comprehensively documents platform functionality, and ongoing email or telephone support when required.

Evaluation of Patient-Centered Outcomes

As REMOTE-CR has been designed to provide an alternative to existing center-based exCR it will be necessary to determine how the program compares with traditional programs before it can be recommended to patients. Therefore, a noninferiority randomized controlled trial comparing mHealth and center-based exCR was planned. This intended evaluation informed aspects of platform and intervention content design, such as exercise prescription, monitoring and coaching, intervention content, and intervention duration. The planned evaluation is in progress, and in-line with the adopted mHealth development framework [38], it will assess patient-centered outcomes such as participation, physical activity level, exercise capacity, modifiable cardiovascular risk factors, quality of life, cost, and cardiovascular events. Further details are provided in the trial protocol [36].

Results

Previous mHealth exCR platforms have provided limited exercise monitoring, feedback, and coaching capabilities, and this may limit intervention effectiveness in terms of exercise-induced risk factor modification [27]. To address these limitations, REMOTE-CR integrates advances in wearable sensor and mobile communications technologies to provide enhanced exercise training and physical activity behavior change capabilities, similar to those provided by traditional center-based exCR programs. The REMOTE-CR platform design is described in detail below.

Platform Components

The REMOTE-CR platform comprises a commercially available Android-based smartphone mobile phone and wearable sensor, custom smartphone and Web-based apps, and a custom middleware platform (Figure 1).

Smartphones were considered to be the optimal communication platform as near ubiquitous mobile broadband availability in many developed countries allows mHealth exCR to be delivered to patients in almost any location. The Android smartphone operating system (Google Inc., USA) was selected as the basis for the REMOTE-CR smartphone app as it has a majority share of the smartphone operating system market [56] and the widest range of handsets, including many low-priced models. These attributes ensure REMOTE-CR could be accessible to a broad range of patients, and will aid translation into practice.

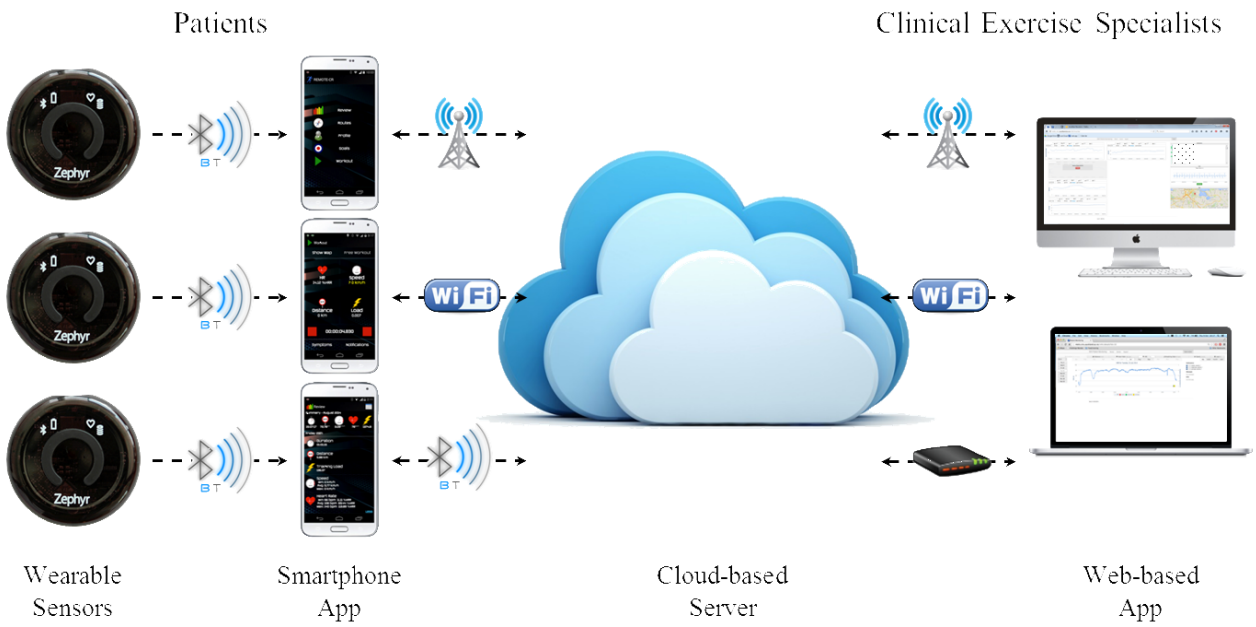
The BioHarness 3 wearable sensor (Zephyr Technology, USA) was selected because its multisensor array is well suited for monitoring exercise among CHD patients, inbuilt Bluetooth connectivity enables integration with almost all current smartphones and commercial availability will assist accessibility and translation into practice. The BioHarness sensor array quantifies electrocardiogram (ECG, including waveform data), heart rate, heart rate variability, respiratory rate, torso posture, and triaxial acceleration. The capability to monitor heart rhythm in addition to the more ubiquitous heart rate, and respiratory rate were considered advantageous for monitoring cardiovascular workload during exercise among CHD patients. While previous versions of the BioHarness have been validated [57-62], a validation of the BioHarness 3 was conducted as part of the REMOTE-CR development process [35].

The custom software components of the REMOTE-CR platform include a middleware named Odin, a patient-facing Android smartphone app, and a clinical exCR specialist-facing Web-based app. All software components were designed and built by the research team. The Odin middleware links smartphone and server-side software to manage communication and logistic functions including data security, network connectivity, and device resource usage [63,64]. By addressing low-level functionalities, Odin enabled development of the patient- and specialist-facing apps to focus on optimizing features for mHealth exCR. Furthermore, iterative middleware refinements can be rapidly integrated into the REMOTE-CR platform without requiring substantial changes to the smartphone or Web-based apps.

The REMOTE-CR smartphone app [65] has been built for Android version 4.0 or higher, which includes most Android smartphones released since 2012. The smartphone app underwent an iterative development process, and was included in the validation of the REMOTE-CR platform in order to determine real-time data transmission reliability [35]. The Web-based app is accessible via any Internet browser, including desktop and mobile browsers, and does not require installation of specialized software. This enables true mobile capability for

both patient- and specialist-facing apps, and allows the REMOTE-CR platform to operate from any location where the patient and specialist have a mobile or local Internet connection. To address the overall design objectives, the smartphone and Web-based apps were designed to include components that enable real-time remote exercise monitoring and coaching, retrospective exercise performance review, goal setting, behavior change education, and social support. Descriptions of specific components of the smartphone and Web-based apps are provided below, and include links to the underlying theory- and evidence-based constructs. Related patient- and specialist-facing components have been described together to reinforce the connected, interactive context of the platform.

Figure 1. REMOTE-CR platform schematic.



Real-Time Remote Exercise Monitoring and Coaching

Exercise monitoring and coaching capabilities have been modeled on center-based exCR, where exCR specialists provide patients with face-to-face supervision, individualized coaching, behavior change education, and social support. Real-time remote exercise monitoring and coaching allows more responsive and individualized management of patients' exercise training in comparison to previous telehealth exCR platforms, which commonly enable only periodic interaction between specialists and patients, based on asynchronous measurement of physical activity level or exercise adherence. Responsive supervision and coaching will help maximize the benefits of exercise with gradual and appropriate progression of exercise prescription parameters, and teach patients how to manage their exercise within suitable ranges of duration and intensity level [20].

A dedicated exercise monitoring component of the patient-facing smartphone app receives wearable sensor data via Bluetooth. Sensor data are displayed continuously alongside geolocation data (provided by the smartphone) and an aggregate measure of training load (ie, exercise dose) [66]. The display configuration can be customized to suit patients' preferences (Figure 2). Patients initiate real-time data transmission to a secure remote Web server when ready to begin exercise, and are greeted with a message from exCR specialists that includes individualized exercise prescription parameters and behavior change content. Patients continue to receive individualized messages from exCR specialists via the smartphone app throughout exercise; messages include coaching, feedback about adherence to individualized exercise prescription parameters, encouragement, and social support.

Real-time interaction allows responsive modification of exercise behavior and provision of individualized competence information that supports exercise-related confidence (ie, self-efficacy, perceived competence). Immersive real-time social support is expected to enhance perceptions of relatedness. Remotely monitored exCR inherently supports perceived autonomy in a way that face-to-face supervision may not, as patients will develop exercise behaviors in real-world environments that remain accessible beyond the program duration. This may streamline the transition to independent exercise, and promote long-term exercise adherence.

Patients can report cardiovascular symptoms including angina, dyspnea, and light headedness during exercise, using an accepted clinical symptom rating scale that has been adapted for use on smartphones [67]. ECG waveform data are not transmitted continuously in order to manage mobile broadband bandwidth requirements, but all symptom reports are accompanied by an ECG rhythm strip and exCR specialists can access on-demand ECG data whenever required via the Web-based app.

The exercise monitoring component of the specialist-facing Web-based app continuously retrieves patients' exercise data from a secure Web server and visualizes them for real-time review. ExCR specialists view patient data within individual monitoring panes that display instantaneous data for all exercise variables and a configurable time-series graph to enable trend analysis. Simultaneous monitoring of multiple patients is

supported. Exercise intensity level is displayed as a percentage of heart rate reserve (%HRR, the proportional difference between rest and maximal exercise heart rates) [68], which is a more accurate indicator of metabolic demands than the percentage of maximal heart rate [69,70]. Furthermore, this method simplifies individualization of exercise prescription as exCR specialists are not required to recall resting and maximal exercise data for each participant. If required, parameters that underpin %HRR can be edited in the smartphone app. Separate monitoring panes in the Web-based app display patients' location, notification events, and on-demand ECG data (Figure 3). Location monitoring enables exCR specialists to consider effects of terrain on exercise responses, integrate local terrain into exercise prescription management, and provide accurate information if an emergency response is required. Notification events include newly initiated exercise training sessions, individualized exercise threshold alerts, and patient-reported cardiovascular symptoms. Exercise alert thresholds can be used to identify patients who are noncompliant with prescribed exercise parameters [67] and improve efficiency during multipatient monitoring by allowing exCR specialists to prioritize attention on patients who need the closest supervision.

The Web-based app enables exCR specialists to provide patients with real-time individualized coaching, feedback, social support, and instructions related to cardiovascular symptoms via a text-to-audio messaging system. Written messages are processed by a text-to-audio converter before being presented to patients in real time, typically via earphones. Audio messages will enhance patients' perceptions of relatedness as they can closely approximate interaction provided during center-based exCR. Audio messages help preserve the real-time context of the message content, and enhance usability by eliminating the need for patients to manually check message content via the smartphone. Patients can manually replay audio messages and review message text during exercise, if required.

Real-time exercise monitoring and coaching features integrate behavior change techniques [45] including behavior goal setting, feedback on behavior, biofeedback, social support (unspecified and emotional), instruction on how to perform a behaviour, information about health consequences, behavioral practice/rehearsal, graded tasks, credible source of information, social reward, and verbal persuasion about capability.

Evidence-Based Clinical Exercise Prescription

Exercise intervention content is informed by evidence-based guidelines for prescribing exercise to cardiac patients [20,67]. Consistent with American College of Sports Medicine guidelines [67], the REMOTE-CR exercise program comprises three training sessions per week for 12 weeks, and encouragement to be active on most week days (ie, ≥ 5 days). Exercise prescription parameters are individualized and progressed based on patients' maximal aerobic exercise capacity (O_2max), exercise-induced signs and symptoms, age, sex, and exercise tolerance throughout the program. Patients with higher baseline O_2max and no inducible signs or symptoms begin with a more challenging exercise prescription than those with lower capacity and/or inducible signs or symptoms. Exercise duration ranges from 30–60 min and includes warm-up and cool-down phases to allow appropriate cardiovascular and musculoskeletal preparation and recovery. Exercise intensity level ranges from 40–65% HRR, and is adjusted to optimize physiological adaptations while remaining below a metabolic load that induces abnormal clinical signs or symptoms (if present). REMOTE-CR was designed to focus on aerobic exercise modes such as walking, cycling, and stationary ergometry (eg, rowing, elliptical training). Underwater activities are not supported as wireless communications (eg, Bluetooth, mobile broadband) do not function underwater. Strength and neuromuscular training are recommended components of exCR [67] but existing sensor technologies are incapable of quantifying these modes; this remains an important challenge for mHealth exCR to overcome. The REMOTE-CR platform architecture has been designed to enable rapid integration of additional data sources whenever the appropriate sensor technologies become available.

Figure 2. REMOTE-CR mobile phone app screenshots.

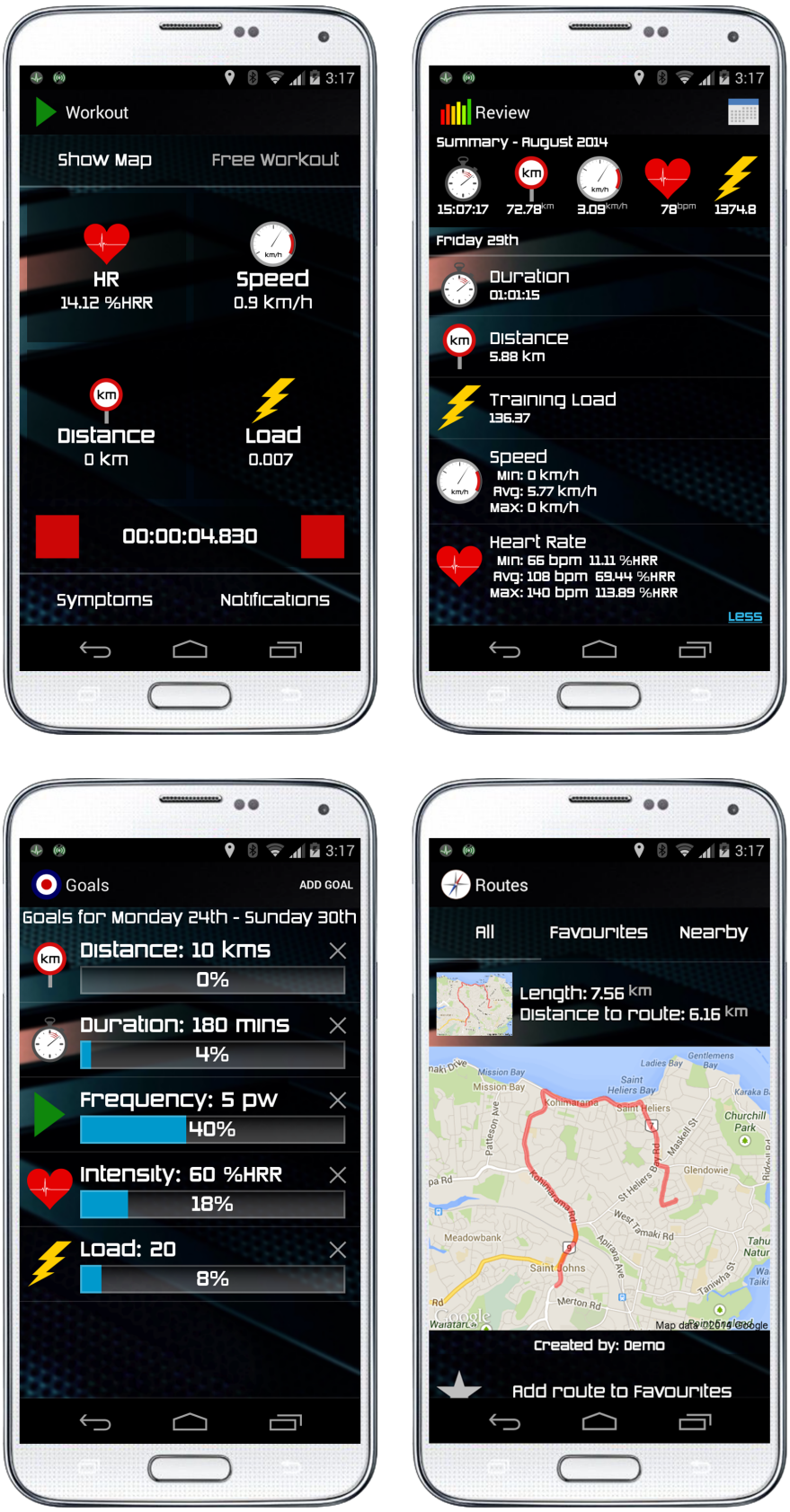
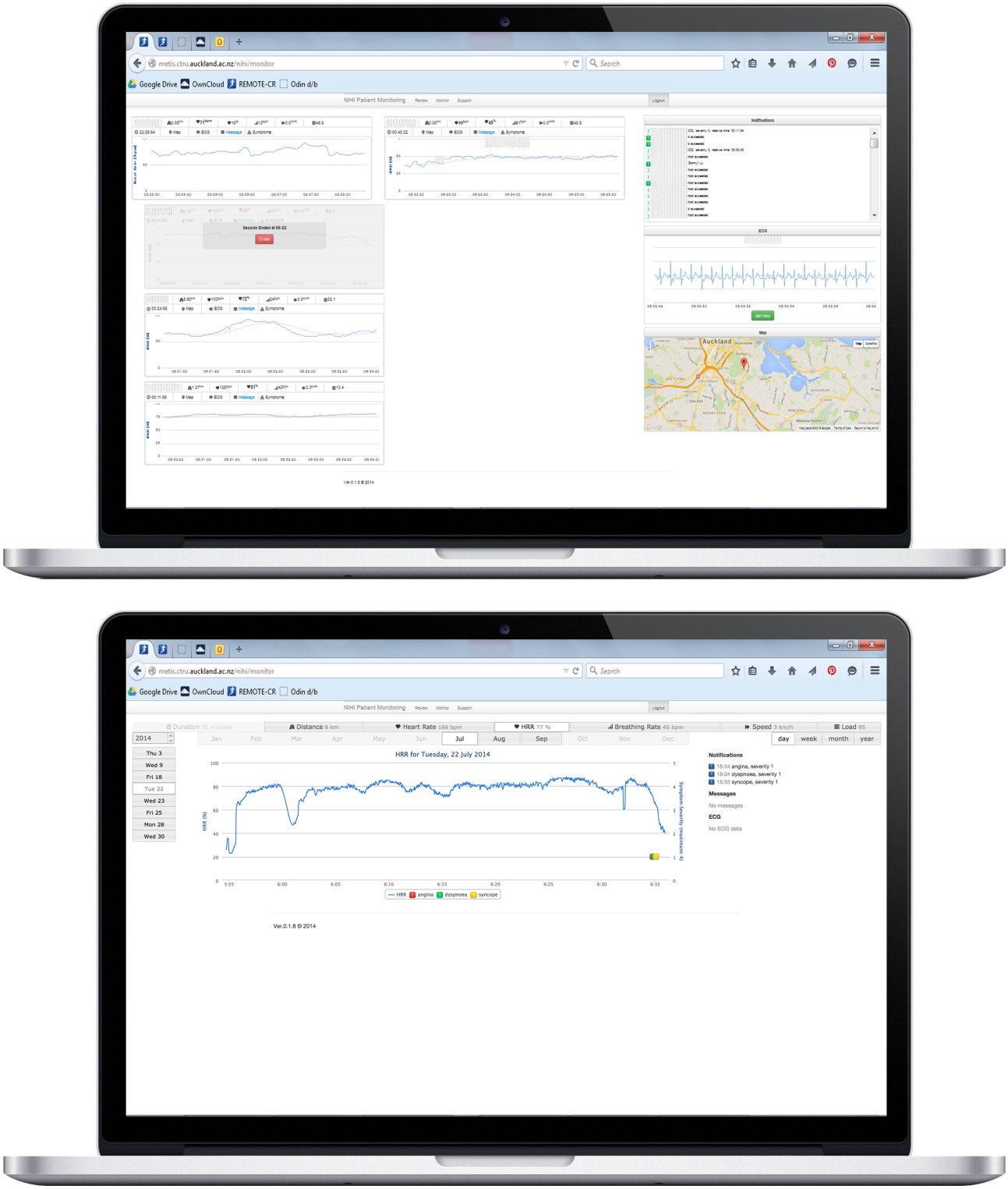


Figure 3. REMOTE-CR web-based app screenshots.



Exercise Performance Review

The patient-facing smartphone app and specialist-facing Web-based app both include dedicated components for retrospectively reviewing exercise performance data. Both components synchronize with a secure Web server; data presentation varies to suit differing needs of patients and exCR specialists. The patient-facing smartphone app summarizes exercise duration, distance, speed, heart rate reserve, training load, received messages, reported symptoms, and location for each training session. Information is also aggregated over calendar months (Figure 2).

The specialist-facing Web app allows exCR specialists to view full resolution data for each training session, including cardiovascular symptoms and ECG, and summarizes patients' compliance with individualized exercise prescription parameters (Figure 3). These data allow exCR specialists to review patients' adherence to exercise prescription goals, can inform decisions about the individualized progression of exercise prescription

parameters, and help to identify patients who may need additional support. Web-based app performance review features also allow exCR specialists to review data recorded outside scheduled real-time monitoring operating hours. This provides additional flexibility for patients and may help to sustain regular exercise, while still enabling exCR specialists to track patients' performance. Similar to previous telehealth exCR programs, specialists are able to communicate with patients who predominantly exercise outside real-time monitoring windows via telephone, SMS, or email.

Patient- and specialist-facing exercise performance review features provide information that will inform patients' perceptions of self-efficacy and competence, and integrate behavior change techniques [45] including reviewing behavior goals, monitoring behaviours without feedback, feedback on behaviour, self-monitoring (behavior, outcomes of behavior), and biofeedback.

Goal Setting

Goal setting components are included in both the patient-facing smartphone app and the specialist-facing Web-based app. Patients are able to set individualized weekly goals related to exercise parameters such as duration, frequency, distance, level of intensity, and training load (Figure 2). Goal achievement feedback is automated based on recorded exercise performance data; visualized feedback is updated weekly to reflect current goal achievement. Goal setting, though not compulsory, is encouraged during the initial training module and throughout the program via behavior change education content (described below). Patients can create, edit, and remove goals at any time.

ExCR specialists can set goals in conjunction with individualized exercise prescription and/or physical activity recommendations. Visual feedback is presented for short- and long-term goal achievement in order to facilitate monitoring of patients' adherence to prescribed exercise volumes and recommended physical activity levels.

Patient- and specialist-facing goal setting features are discrete; that is, specialists do not see patients' goals and vice versa. This allows patients to take ownership of goal setting, and individualization will help ensure goals enhance motivation. Similarly, exCR specialists can monitor patients' performance against evidence-based exercise prescription parameters and physical activity guidelines. This helps exCR specialists to optimize exercise prescription, coaching, and behavior change content for individual patients. Patient and specialist goals can be reset or modified as required to align with progress throughout the program and maintain an optimal motivational effect.

Goal setting features support patients' perceptions of autonomy, competence, and self-efficacy, and integrate behavior change techniques such as goal setting (behaviour, outcomes of behaviours), reviewing behavior goals, and reviewing discrepancies between current and goal behaviors.

Behavior Change Messages

A suite of behavior change messages are delivered to patients as audio messages throughout the exercise program. Messages are received during exercise, and can be reviewed at any time as part of the exercise performance review features described above. Message content was adapted from previous mHealth CR interventions designed for delivery via SMS [71,72] that have demonstrated positive effects on lifestyle behaviors [27,73], was grounded in behavior change theories, and integrated feedback from CR patients [55]. SMS message tone was adapted for the real-time conversational context of REMOTE-CR, and also took advantage of the larger character allowance to include more natural language. Messages aimed to enhance patients' perceptions of exercise self-efficacy, competence, and relatedness, and integrated behavior change techniques [45] including problem solving, outcome goal setting, action planning, reviewing behavior goals, self-monitoring (behavior, outcomes of behavior), social support (unspecified and emotional), instruction on how to perform a behaviour, information about health consequences, generalization of a target behavior, information from a credible source, self-reward, framing/reframing, verbal persuasion about capability, and focus on past success.

Social Support

In the current REMOTE-CR implementation, social support is provided via real-time exercise coaching and behavior change messages, as described above. A dedicated social support component was also designed, but has not yet been implemented. Social support, from other cardiac patients in particular, is a highly valued aspect of CR [55]. Smartphone app features were designed to enable patients to interact with each other, both via the REMOTE-CR platform and face-to-face. Prototype social support features include a secure, closed social network, and location aware filtering of exercise route mapping (Figure 2). Social network functionality was designed to allow both individual and group communication in order to share experiences, provide encouragement, discuss queries or problems, offer advice, and organize face-to-face meetings if desired. Location aware filtering of exercise route maps was designed to help identify patients who exercise in close proximity to each other, and promote opportunities to exercise together and/or organize face-to-face meetings.

Social support features were designed to support patients' perceptions of self-efficacy and relatedness, and integrate behavior change techniques [45] including social support (unspecified, emotional).

Security

To ensure privacy, the REMOTE-CR platform requires user accounts to be registered into a database on a secure Web server; access to the database is limited to the study team. The patient-facing smartphone app is publicly available via the Google Play Store [65]. Smartphone and Web-based app functionalities are contingent on authentication with the secure Web server to prevent unauthorized use of the REMOTE-CR platform, and all data transmission is encrypted. Planned improvements include integrating the secure hypertext transfer protocol for smartphone–Web-server communication, and the OAuth protocol for Web-based app–Web server communication.

Discussion

This article outlines the development of an evidence- and theory-based mHealth exCR platform that provides real-time remote exercise monitoring and coaching, social support, and behavior change education. Rather than redesigning the fundamental exCR process, REMOTE-CR aimed to close the current gap between center- and home-based exCR programs by mobilizing the expertize of exCR specialists. Advanced wearable sensor and smartphone technologies overcome common accessibility barriers that limit center-based exCR participation, while preserving clinical oversight that is commonly recommended in exCR guidelines [4,20,39]. In doing so REMOTE-CR provides an alternative delivery model that may help to broaden the reach of exCR by meeting the needs of patients who are unable or unwilling to attend traditional center-based exCR programs. It should be noted that REMOTE-CR was not designed to replace existing exCR programs; rather, it was designed to complement center-based programs, and may augment home-based programs that do not currently provide clinical exercise supervision.

Principal Findings

REMOTE-CR builds on previous telehealth exCR platforms that have commonly relied on periodic telephone, email, or SMS interaction between patients, and exCR specialists and/or clinicians [21-31]. By enabling more responsive (ie, real-time) and individualized management of patients' exercise programing, and more immersive social support during exercise, the REMOTE-CR platform may provide a more engaging environment that promotes positive motivational, behavioral, and physiological outcomes.

While real-time exercise monitoring and coaching was the primary design focus, the REMOTE-CR platform also includes a strong theoretical foundation. Many elements of the platform design and intervention content are grounded in behavior change theories that aim to enhance patients' self-efficacy, competence, autonomy, and relatedness. This empowering approach is expected to build confidence and resilience [20], which may favor sustained positive exercise behaviors throughout and beyond the duration of the exCR program. Further, adoption of evidence-based clinical exercise prescription and monitoring guidelines [67] will help to ensure patients accrue a sufficient exercise dose to stimulate positive physiological adaptation, and provide attainable exercise targets that will support perceived self-efficacy and competence via performance accomplishments [55].

The REMOTE-CR platform was designed to enable rapid and cost-effective scalability. Rural and remote populations have reduced access to specialist services [74] and use of Internet-based services allows distribution of clinical expertise from centralized (often metropolitan) exCR facilities across geographically diverse populations. Centralized management of geographically diverse platform deployments may be a more cost-effective way to increase the reach of exCR compared with establishment of additional center-based facilities. In addition to staff time, hardware (ie, smartphone and wearable sensor) and mobile broadband subscriptions are the main operating costs. Increasingly ubiquitous smartphone ownership and mobile broadband access [32-34], and declining mobile broadband costs [75] may reduce operating costs in future; the REMOTE-CR smartphone app [65] can be installed on patients' personal smartphones (which may promote usability), and the bandwidth requirements are low (approximately 2–4 $MB \cdot h^{-1}$). Use of a commercially available wearable sensor also enhances scalability.

Limitations

While the theory- and evidence-based REMOTE-CR platform provides exciting opportunities to improve the provision and uptake of exCR services, it is not free from limitations. The REMOTE-CR platform achieved the primary objective to provide comprehensive exercise training and behavior change features, but does not currently include all core CR components recommended by international guidelines [4,39]. The platform architecture has been designed to enable modular integration of additional CR components in future, and may be expanded to create a more comprehensive CR program. At present, patients may still access additional CR components via traditional channels such as outpatient clinics and group seminars. Learning to use the smartphone and wearable sensor components of the platform represent potential barriers for CHD patients who are typically of older age. The smartphone app user interface was designed to simplify navigation, and a dedicated training module was developed to familiarize patients with the technologies; however, it is possible that some patients may not be able to overcome the technological barriers. Increasing smartphone use among older age groups [34] suggests this may be a relatively short-term barrier, but reinforces a need to retain existing exCR services to provide options for all patients. It is difficult to keep pace with rapidly advancing smartphone and wearable sensor technologies. The REMOTE-CR smartphone app was initially designed for Android 4.0, but remains compatible with all subsequent updates (v4.0–5.1). Moreover, the flexible platform architecture enables rapid integration of new smartphone and wearable sensor capabilities as they become available.

The development framework adopted for this work recommends mHealth platforms should be rigorously evaluated in studies that use randomized controlled trial design and include patient-centered outcomes to evaluate physical, mental, and social health outcomes [38]. The REMOTE-CR platform is being evaluated in a noninferiority randomized controlled trial comparing mHealth and center-based exCR programs [36]. The study will assess the effectiveness and acceptability of the REMOTE-CR platform among a CHD population; study outcomes include O_2max, modifiable cardiovascular risk factors (blood pressure, blood lipid and glucose concentrations, body composition, physical activity energy expenditure), exercise-related motivational factors, HRQoL, and satisfaction with the REMOTE-CR platform. The results of this study will help to determine whether real-time remotely monitored exCR can provide similar benefits compared with center-based programs and, therefore, whether it represents a suitable alternative for patients whose needs are not met by existing services. If proven effective, remotely monitored exCR may

offer a more cost-effective model for expanding the reach of exCR compared with the establishment of additional center-based facilities. Mobile technologies provide an ideal platform for the provision of real-time exercise-based CR and could easily be applied to other chronic disease prevention and management.

Authors' Contributions

JR was primarily responsible for designing the mHealth platform. AM was primarily responsible for technical development. RM, IW, and NG assisted with design and technical development. All authors contributed to the preparation and final approval of the manuscript. We (authors) accept accountability for all aspects of the work.

Conflicts of Interest

None declared.

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Abbreviations

CHD: coronary heart disease
CR: cardiac rehabilitation
ECG: electrocardiogram
exCR: exercise-based cardiac rehabilitation
HRR: heart rate reserve (difference between resting and maximal heart rates)
HRQoL: health-related quality of life
mHealth: mobile health
REMOTE-CR: remote exCR platform
SMS: short message service
O_2max: maximal aerobic exercise capacity

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Original Paper

A Mobile App Development Guideline for Hospital Settings: Maximizing the Use of and Minimizing the Security Risks of "Bring Your Own Devices" Policies

Soleh U Al Ayubi[1], PhD; Alexandra Pelletier[1], MBA; Gajen Sunthara[1,2], MS; Nitin Gujral[1], MBA; Vandna Mittal[1], MPH; Fabienne C Bourgeois[3], MPH, MD

[1]Innovation & Digital Health Accelerator, Boston Children's Hospital, Boston, MA, United States

[2]United States Digital Service, The White House, Washington, DC, United States

[3]General Pediatrics, Boston Children's Hospital, Boston, MA, United States

Corresponding Author:
Soleh U Al Ayubi, PhD
Innovation & Digital Health Accelerator
Boston Children's Hospital
Landmark Center, 7th Floor, 7399.2
300 Longwood Ave
Boston, MA, 02115
United States
Phone: 1 8572183242
Fax: 1 6177304838
Email: soleh.alayubi@childrens.harvard.edu

Abstract

Background: Hospitals today are introducing new mobile apps to improve patient care and workflow processes. Mobile device adoption by hospitals fits with present day technology behavior; however, requires a deeper look into hospital device policies and the impact on patients, staff, and technology development. Should hospitals spend thousands to millions of dollars to equip all personnel with a mobile device that is only used in a hospital environment? Allowing health care professionals to use personal mobile devices at work, known as bring-your-own-device (BYOD), has the potential to support both the hospital and its employees to deliver effective and efficient care.

Objective: The objectives of this research were to create a mobile app development guideline for a BYOD hospital environment, apply the guideline to the development of an in-house mobile app called TaskList, pilot the TaskList app within Boston Children's Hospital (BCH), and refine the guideline based on the app pilot. TaskList is an Apple operating system (iOS)-based app designed for medical residents to monitor, create, capture, and share daily collaborative tasks associated with patients.

Methods: To create the BYOD guidelines, we developed TaskList that required the use of mobile devices among medical resident. The TaskList app was designed in four phases: (1) mobile app guideline development, (2) requirements gathering and developing of TaskList fitting the guideline, (3) deployment of TaskList using BYOD with end-users, and (4) refinement of the guideline based on the TaskList pilot. Phase 1 included understanding the existing hospital BYOD policies and conducting Web searches to find best practices in software development for a BYOD environment. Phase 1 also included gathering subject matter input from the Information Services Department (ISD) at BCH. Phase 2 involved the collaboration between the Innovation Acceleration Program at BCH, the ISD Department and the TaskList Clinical team in understanding what features should be built into the app. Phase 3 involved deployment of TaskList on a clinical floor at BCH. Lastly, Phase 4 gathered the lessons learned from the pilot to refine the guideline.

Results: Fourteen practical recommendations were identified to create the BCH Mobile Application Development Guideline to safeguard custom applications in hospital BYOD settings. The recommendations were grouped into four categories: (1) authentication and authorization, (2) data management, (3) safeguarding app environment, and (4) remote enforcement. Following the guideline, the TaskList app was developed and then was piloted with an inpatient ward team.

Conclusions: The Mobile Application Development guideline was created and used in the development of TaskList. The guideline is intended for use by developers when addressing integration with hospital information systems, deploying apps in

BYOD health care settings, and meeting compliance standards, such as Health Insurance Portability and Accountability Act (HIPAA) regulations.

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KEYWORDS

BYOD; guideline; safeguard; custom application; hospital settings; security; privacy; mobile application; electronic medical records

Introduction

Smartphones help individuals perform many functions and are now considered a critical tool in some workplaces. In the United States, smartphone market penetration reached 74% to 77% in the 3rd quarter of 2015 [1,2]. In health care, the market penetration is higher; smartphones were adopted by 96% of physicians [3]. Health care professionals are relying more on their smartphones to access medical information, clinical tools, or patient information [4-10]. According to a recent study [11], 89% of health care workers use their smartphone for work purposes, and another survey [3] found that 96% of physicians interviewed used smartphones as their primary device to support clinical communications. Of the 130 hospitals in the United States, 85% (111/130) support the use of personal devices, including smartphones, at work [12]. The ability for professionals to use their personal mobile devices at work is widely known as bring-your-own-device (BYOD).

As BYOD becomes more popular across industries, hospitals are also beginning to adopt BYOD policies for health care staff. The explosive adoption of mobile device usage by health care professionals [3,13] has led to the growth of new patient care mobile apps that are having positive impact on patient care [4-8,10,14-17]. Implementing BYOD eliminates the need for organizations to purchase mobile devices and saves money in the long run. By embracing a more mobile workplace, health care organizations can support the work demand of staff that works across multiple clinics and hospitals. However the adoption of BYOD increases in hospital settings, challenges still exist in the areas of privacy-security compliance and information technology (IT) management.

A number of privacy-security compliance risks arise when applying BYOD to health care environments. For instance, if a user is interacting with their mobile device in a hospital to retrieve protected health information (PHI), security risks may emerge if sensitive data is exposed. As a result, BYOD has created security concerns for many hospitals. A survey revealed 53% of health care professionals used smartphones or tablets for work purposes through unsecured WiFi networks; 41% of the devices were not password protected; and only 52% reported having the Bluetooth discoverable mode disabled on their smartphones [11]. As BYOD becomes more of an established policy at hospitals, hospital IT departments will need to manage a large variety of mobile devices that require hospitals to increase technical support resources in already resource-constrained hospital IT departments.

Nevertheless, BYOD is inevitable; health care organizations should focus on how to enable effective and efficient BYOD policies rather than to restrict the use of personal mobile devices. Several approaches exist to limit security risk and create an acceptable use of BYOD in health care settings. A few highlighted methods include: (1) incorporating BYOD policy text within employment agreements, (2) developing mobile device management (MDM) procedures, and (3) developing guidelines for how mobile apps should be developed to minimize security risks. First, health care organizations need to develop clear guidance for employees on how to use personal mobile devices for work (ie, texting, pictures). At health care organizations, incorporating these clear policies within employment agreements will help stress the importance of maintaining care and confidentiality when handling PHI. Second, leveraging MDM technology helps secure, monitor, manage and support mobile devices across enterprises. MDM functionalities typically include over-the-air (OTA) distribution of apps, data and configuration settings, and security settings for mobile devices. The functionalities were designed with the intent to minimize operational costs, system downtime, and business risks [18]. Third, a framework for hospital employees developing mobile apps will help address the needs to design and develop the mobile app to protect PHI.

The first two approaches have been developed and widely implemented [12,19]. Whereas the first two approaches do not cover the issues of custom mobile apps complying with BYOD concerns and policies, the third approach provides the opportunity to focus on identifying technological development methods that fit within the concerns and policies. Unfortunately, unlike the first two approaches, the technological development approach is still a domain that is being defined. Therefore, this paper is written with the purpose to fill the gap by proposing a guideline that can be used by app developers, designers, and product managers to develop apps complying with BYOD and associated hospital security risks. This paper offers a descriptive guideline on how mobile apps can be designed for hospital BYOD environments while maintaining their existing security policies per Health Insurance Portability and Accountability Act (HIPAA) regulations. The proposed guideline applies only to tablets, mini tablets, and smartphone devices. Due to the maturity of security measures already established and the ease of authentication requirements and usability compared with other mobile devices, laptops will not be included in this paper. To focus the scope of the guideline, other handled devices will also not be included.

Methods

Development

Multiple steps were taken to develop the Boston Children's Hospital's (BCH) BYOD mobile application development

guideline. The steps include understanding the current standards and taking into consideration established policies within hospital settings through Internet research. The research established the theoretical and practical foundation of how to go about creating apps within a BYOD environment. The study led to identifying potential BYOD risks when accessing patient information, understanding how other organizations developed their BYOD guidelines and risks associated with them, and developing potential solutions and recommendations for a hospital-appropriate mobile app development guideline for BYOD. After conducting this research, discussions were conducted with both external and internal security professionals and the team interviewed Information Services Department (ISD) leaders at BCH. Finally, we developed a hospital mobile app development guideline and named it BCH BYOD Mobile Application Development Guideline.

Implementation

After establishing the guideline, the team developed a mobile app, called TaskList, which could adhere to the privacy and security concerns related to BYOD in health care settings. TaskList is an Apple operating system (iOS)-based app designed for medical residents at BCH to monitor, create, capture, and share daily collaborative tasks associated with patients [20]. The TaskList app is integrated with the electronic medical record (EMR), Cerner and EPIC systems, BCH email system, and BCH lightweight directory access protocol (LDAP) authentication system. Cerner and EPIC systems offer an integrated suite of software that support functions related to patient care and hospital operation, such as patient registration and scheduling, clinical systems for providers, administrative systems for pharmacists, and billing systems for insurers. BCH is a leading pediatric hospital serving as one of the largest pediatric medical centers in the United States [21]. It offers a full range of health care services for infants, children, and adolescents [21]. The hospital has over 5500 mobile devices connected to its network, the majority of which are employee-owned iPhones and iPads. Due to the popularity of BYOD at BCH, TaskList proved to be an appropriate test case to determine app requirements within a BYOD environment and to test the BCH BYOD Mobile Application Development Guideline.

Results

BCH BYOD Mobile Application Development Guideline

From our research and subject matter interviews externally and internally to BCH, we created 14 practical recommendations for the BCH BYOD guideline. Table 1 describes each recommendation and how it relates to developing a mobile app.

Table 1. Summary of BCH BYOD guideline to safeguard custom application in hospital settings.

No.	Risks	Guidelines and Recommendations
1	Unauthorized access to app and decreased productivity	Adopt enterprise-standards but usable authentication
		Implement RBAC[a]
2	Unauthorized access to data	Implement at least three layers of security on data transmission (transport layer security, access control, and content security)
		Allow apps to work on internal networks or VPN[b] only
3	Data transmission to unauthorized parties	Protect the mobile app's notifications
4	Unauthorized access to apps and data	Prevent apps from working on jail-broken devices
		Allow apps to only work on encrypted-devices or devices with pass-codes
5	Unauthorized access to data	Require apps to use minimal cache
6	Unauthorized access to the app	Enforce automatic logoff
7	Data transmission to unauthorized parties	Limit copy data and print screen functionalities
		Limit backup on Cloud services
8	App distribution to unauthorized parties	Distributing the app: Implement internal over-the-air installation and app updates
9	Unauthorized access to app	Implement remote wipe out functionality
		Implement ability to disconnect and block a user anytime

[a]role-based access control.

[b]virtual private networks.

Authentication and Authorization

Adopt Enterprise-Standards With Convenient Authentication

User verification is a crucial component of secured systems, especially for medical-related systems. The verification provides access to valuable information and offers personalized services. Most health care systems require individual and enterprise standard authentication with the ability to time-out a user after a period of inactivity. The enterprise authentication procedure at times requires at least three combinations of keyboards (alphabet, numbers, and special characters) that can be cumbersome to switch between when using a mobile device. Because productivity is impaired by these hassles, this barrier should be minimized for clinicians. Designing an authentication process that complies with the required security standards, while still being usable and convenient, should be built into the app.

Implement Role-Based Access Control

Within an organization, are created for various job functions. The permissions and security measures to perform certain operations and access specific features within an app should be assigned based on roles. Employees are assigned particular roles, and through role assignments acquire computer permissions to perform particular computer-system functions. This is widely recognized as role-based access control (RBAC) and has been endorsed by the US government [22,23]. RBAC simplifies security management by providing a role hierarchy structure that eventually reduces a business risk caused by complex user management.

Data Management

Implement at Least Three Layers of Security on Data Transmission (Transport Layer Security, Access Control, and Content Security).

Following a recommendation from the US National Institute of Standards and Technology [22], at least three layers of security measures of data transaction need to be implemented for secure data transmission. This includes using Secure Sockets Layer (SSL) as a data transfer protocol, ensuring timely restricted and authenticated transactions (session-based access as access control), and making the data transferred in the channel securely encrypted (content security). Implementing the three levels of protection layers is one of the simplest-and most important-security measures to reduce the risk of data being accessed and used by unauthorized parties.

Allow Apps to Work on Internal Networks or Virtual Private Networks Only

A virtual private network (VPN) is a group of computing devices (computer, tablet, printer, and mobile phone) networked together over a public network, namely, the Internet. VPN allows devices to connect to remote resources when they are not physically on the same local area network (LAN). VPN enables mobile employees, telecommuters, business partners, and others to take advantage of locally available, high-speed broadband to gain access to the enterprise's network. VPN provides a high level of security, using advanced encryption and authentication protocols to safeguard data from snoops, data thieves, and other unauthorized parties. Limiting the apps to work on internal networks or VPN-only networks assures one simple security practice that prevents unauthorized parties to snoop during data transmission.

Protect the Mobile App's Notifications Appropriately

A good practice is to always secure PHI and to limit sending non-PHI to third parties outside of a hospital network. On mobile devices (tablets or smartphones), an app is designed to be inactive while it is running in the background due to its limited resources. When someone sends a message to an app idling in the background there is no way to deliver that message other than using a push notification feature from its operation system. Examples of notification features include the Apple Push Notification System (APNS) for iOS devices or Google Cloud Messaging (GCM) for Android devices that display limited text on a mobile device's home screen to alert a user that a message is available on the app. In this case, the best practice is to send simple non-PHI content via notifications, for example: "You have a new update." Then, when the user responds to the notification, the app will pull the associated PHI from internal hospital resources and display the PHI to the users. This practice will allow an app to push a notification/message to users without having to breach HIPAA rules by not sending the associated PHI to the third parties.

Safeguarding the App Environment

Prevent Apps From Working on Jail-Broken Devices

Jail breaking is a process used to modify the operating system running on a device. The process includes removing standard-imposed security and restrictions, allowing unsecured or illegal operations, such as installing malicious code or data sniffing code. The jail-breaking process may also cause a device to function incorrectly or stop working. Therefore, including a requirement that health care apps should not operate or function on jail broken devices is mandatory.

Allow Apps to Only Work on Encrypted-Devices or Devices With Pass-Codes

Ideally, in the case where protected medical data has been accessed by unauthorized parties, the data still has one more layer of protection: encryption. The parties will not understand the encrypted data without a proper key to open it. When protected medical data is stolen and not encrypted, the general attorney's office may get involved. Under certain circumstances, data breaches of unencrypted protected medical data are required to be reported to the general attorney's office. In 2009, the US Government enacted the Health Information Technology for Clinical Health Act (HITECH) that requires health care organizations to notify patients if their health records have been compromised. Therefore, preventing the apps from being installed on unencrypted devices is of paramount importance.

Require Apps to Use Minimal Cache

A cache is a temporal repository for stored data that is used to expedite the process of retrieving data from remote storage. Retrieving data can be quicker because an app will check the cache for previously stored information without having to recompute or refetch the data from its original remote locations

(eg, database server). While there are many reasons for using cache in app design, the security threat caching presents is high when handling PHI. Caching increases the risk of unauthorized parties being able to access stored sensitive information. When designing a mobile app within a BYOD environment, it is recommended to use cache in a limited capacity while ensuring quick app performance.

Enforce Automatic Logoff

An automatic logoff functionality will terminate an app when there is no activity on the device, such as screen touch and keyboard activity, after a predefined amount of time. This policy will protect access to the app when the device is intentionally or unintentionally left unattended while the app is open. Another valid security concern results from users leaving their accounts unattended for lengthy periods of time. This situation allows an intruder to take control of the user's terminal, potentially compromising the security of the system. Therefore, defining automatic log off for both the app and account access is an important consideration to ensure accurate authentication and access.

Limit Copy Data and Print Screen Functionalities

In general environment settings, once the information is displayed on a screen, there is no way to prevent users from spreading that information. Nevertheless, there is one way to reduce the risk of data being spread uncontrollably: preventing a user to print the screen. Print-screen is a feature on a mobile device that allows anyone to copy their screen and save it on their device to send to other people. Therefore, designing apps to detect such activity should be required in order to limit the improper dissemination of protected health information.

Limit Backup in Cloud Services

As a standard mechanism for backup data, most mobile devices have an optional cloud-based storage for its apps. Cloud data centers are located all over the world, with a typical customer having limited knowledge as to where the data is actually stored. HIPAA mandates that health care organizations have absolute control of sensitive information. Thus, a feature detecting and preventing mobile devices from storing or backing up sensitive information to its cloud storage is necessary for any clinical app running on a BYOD device unless the organization and their Cloud service providers sign a HIPAA Business Associate Agreement (BAA). A HIPAA BAA is a contract between a HIPAA covered entity such as a hospital and a HIPAA business associate (BA), such as a third party contractor, with the main purpose of protecting PHI in accordance with HIPAA guidelines [24]. This agreement has been a requirement since January 25, 2013 when the US Department of Health and Human Services released the Omnibus Rule, which finalized all the former interim rules for HIPAA and HITECH compliance including that of Cloud data services.

Remote Enforcement

Distributing the App: Implement Internal Over-the-Air Installation and App Updates

General apps for mobile devices are required to be distributed to users through an app market (eg, Apple App Store, Google Play, Windows Phone Store, etc.). However, in many cases, health care apps are designed to be downloaded and installed by hospital employees only and not the public. One solution to the distribution challenge is to attach the device to a development computer, add the device as a development tool, and install the app manually. As the number of users grow, the solution will be tedious and not an efficient distribution process. Therefore, implementing an easy, in-hospital, OTA installation and update process will reduce the burden both on users and IT personnel. Eliminating manual installation lowers the security risk of distributing the mobile app to unauthorized users.

Implement Remote Wipe Out Functionality

Nearly 1.6 million smartphones are stolen annually in the United States [25] and theft of these devices is the number one reason that the integrity of information is compromised [26]. Remote wipe is a security feature that allows an IT administrator or device owner to send a command to a device to delete a device's data. What remote wipe accomplishes can depend on the device, its specific operating system, and any third-party MDM software installed on the device. In an app context, there is one feature called local or auto wipe that clears a mobile device after a prespecified number of failed login attempts, moves outside of a defined physical boundary (geo-fencing), or any other scenarios. Many of the current MDM technologies allows remote wipe of all the data on a device. In some cases, a hospital has the right to wipe out hospital-related data only (a selective folder named sandbox) and not personal data. Thus, designing an app that has the capability to remote wipe a selected folder/data file is of paramount importance, especially when MDM technology is not deployed in the organization.

Implement Ability to Disconnect and Block a User Anytime

Under HIPAA regulations, organizations are required to know which users are accessing PHI and manage their access appropriately. As clinical residents and others change employment status or leave a hospital organization, the need to update each person's role requires the need to update app credentials. This feature may not be available in a current user management system such as active directory. Active directory is a Windows Server feature that allows network administrators to authenticate and manage users. Therefore, implementing a user management dashboard for app administrators to manage (add, disconnect, and delete) users is strongly suggested.

TaskList BYOD Features Based on the Guideline

After the initial research and interviews with IT experts internal to BCH, we applied the BCH BYOD guideline to the TaskList design and development. TaskList incorporated 12 of 15 recommendations.

Authentication and Authorization

Adopt Enterprise-Standards but Convenient Authentication

In TaskList, to develop an authentication with enterprise standards, while still being easily accessible and convenient, we combined BCH enterprise authentication with a personal identification number (PIN). The app requires users to use enterprise authentication to login for the first time. This credential is valid for 24 hours (Figure 1, left) and must be

changed the following day. After a user successfully logs in to TaskList using an enterprise account, the app will ask the user to create a four-digit PIN (Figure 1, middle). If successful, the PIN is valid for 24 hours (Figure 1, middle). Therefore, whenever a user opens TaskList after being logged off (30 minutes of inactivity logs off a user) or after the device is locked, the user would only need to enter the four-digit PIN (Figure 1, right). ISO 9564-1, the international standard for PIN management and security, allows for PINs to between four and 12 digits [27]; but for usability reasons, TaskList uses only four digits which is the most commonly used PIN length [28].

Figure 1. TaskList enterprise authentication and PIN.

Implement Role-Based Access Control

This feature has not been implemented in the TaskList pilot because the users all had the same role. If TaskList should expand beyond the current pilot, role-based access management will be implemented.

Data Communication

Implement at Least Three Layers Of Security on Data Transmission (Transport Layer Security, Access Control, and Content Security)

In TaskList, we implemented Web-service data communication, store and retrieve, which can be accessed through SSL only. This guideline is also part of the BCH data communication standards. In addition, every Web-service call requires a valid session from BCH enterprise accounts as one of the parameters. This allows the app server to check whether the call should be processed or ignored. Only PHI-related information was encrypted to meet encryption guidelines and to balance the resources to encrypt or decrypt.

Allow Apps to Only Work on Internal Networks or Virtual Private Networks

TaskList is able to detect whether it is launched on a BCH internal network (WiFi) or VPN. When the app detects that the access comes from an unsecured network (not internal or VPN), a message pops up alerting users that the app cannot be accessed (Figure 2).

Protect the Mobile App's Notifications

The only external-BCH system that TaskList connects to is the APNS. TaskList may not always be active on a mobile device resulting in the loss of connectivity between the app client and server. When the server sends a notification to the TaskList app in its dormant state, typically APNS is used. To comply with HIPAA, TaskList sends simple non-PHI content via the notifications, such as: "You got a new update" (Figure 3). When the user clicks the notification, TaskList will open from the background and show the information that triggered the notification. This allows the user access to PHI from the hospital network.

System-User Interaction/Local Environment

Prevent Apps From Working on Jail-Broken Devices

TaskList is able to detect whether it is operating on jail-broken devices. When the app detects that the access comes from unsecured devices (jail-broken), a message will pop up and notify users that the app cannot be accessed from the device (Figure 4).

Allow Apps to Only Work on Encrypted-Devices or Devices With Pass-Codes

BCH requires that all laptops and mobile devices connected to BCH network or that are used for BCH-related work must have encryption software installed to protect against potential breaches. Meanwhile, Apple provides a dedicated advanced encryption standard (AES) 256-bit hardware encryption for all data stored on iOS devices [29]. Some iOS apps are designed not to be functional on a device without a passcode and have

the ability to display a message saying that this app only runs on passcode protected devices. For the TaskList project, passcode detection and restriction were not implemented because we required the app to only function when connected to the BCH network profile. The profile forces all mobile devices to have a passcode to access the BCH internal network and VPN.

Enforce Apps to Work With Minimal Cache

Caching leads to security issues while at the same time providing convenience in improving access speed to end users. In the TaskList app, three levels of cache were designed. Level 1: iOS standard cache means that the app allows an iOS to manage its cache; Level 2: on-memory only cache allows the cache to be stored on the device's memory (not on the hard disk), whenever the memory is full or the app is closed, the cache will be erased; Level 3: no-cache implies that every time data is needed, it will be pulled from the original source. On a standard operation, when the delay to pull and process data is generally accepted by users (less than 15 seconds to populate rarely accessed data such as patient lists and less than 1 second to populate other data), then the ability to have no cache is balanced with performance expectations. The TaskList app is setup to use no cache (Level 3).

Enforcing Automatic Logoff

In the TaskList app, the automatic logoff feature will terminate the app when there is no touch on a device screen after 30 minutes (Figure 5). If it is also within the 24-hour authentication window, a new PIN login will be prompted for the user.

Limit Copy Data and Print Screen Functionalities

In the TaskList project, when users are detected using the print screen operation (clicking the home and device power buttons together) a message is displayed informing the user that print screen cannot be done. This will not prevent, but does limit the unauthorized spread of information.

Limit Backup on Cloud services

As TaskList does not store any data locally on devices and uses no-cache, the feature that prevents storing/backup data on the Cloud was not implemented. In the future, when many departments join the pilot, the data get bigger and more time is needed to load the data from server. Consequently, storing some of the data locally on devices and using on-memory cache and preventing backup the data to Cloud services are required.

Remote Enforcement

Distributing the App: Implement Internal Over-the-Air Installation and App Updates

TaskList was developed using iOS that would typically imply the need to distribute the app via the iOS App Store. However, because the app was only for BCH employees, an internal OTA installation and update system was developed (Figure 6). It reduced the burden on both the users and IT.

Figure 2. Tasklist runs on secured network only.

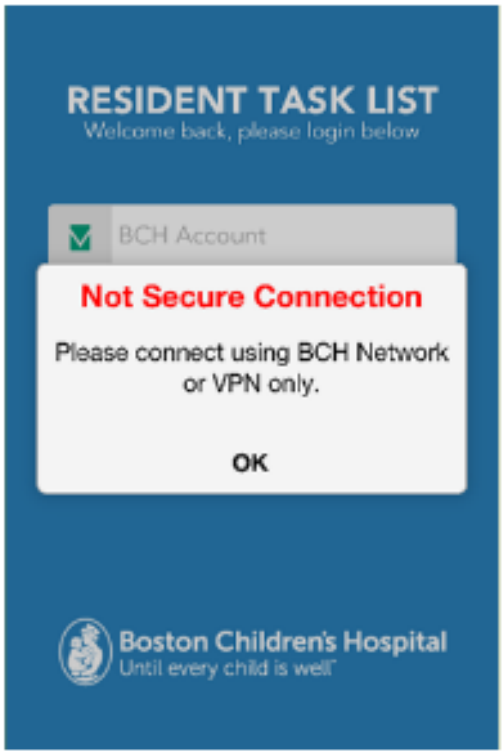


Figure 3. Tasklist limited notifications.

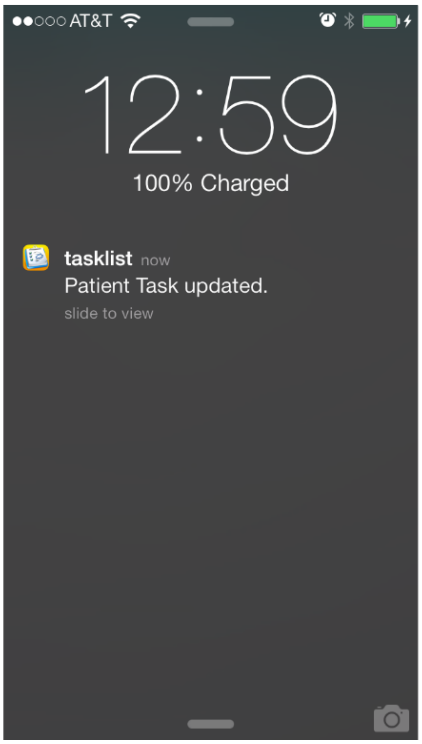


Figure 4. TaskList does not run on jail-broken devices.

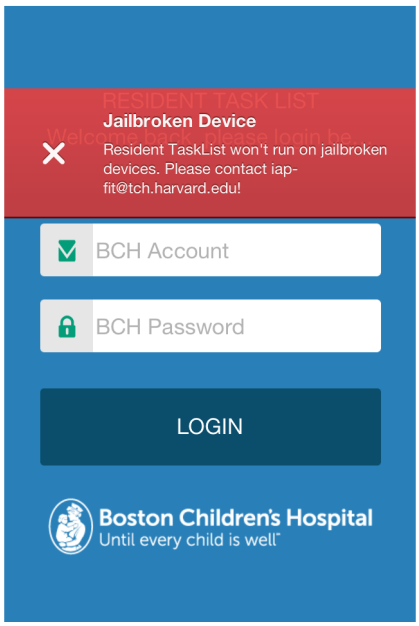


Figure 5. TaskList will be closed after 30-minute of inactivity.

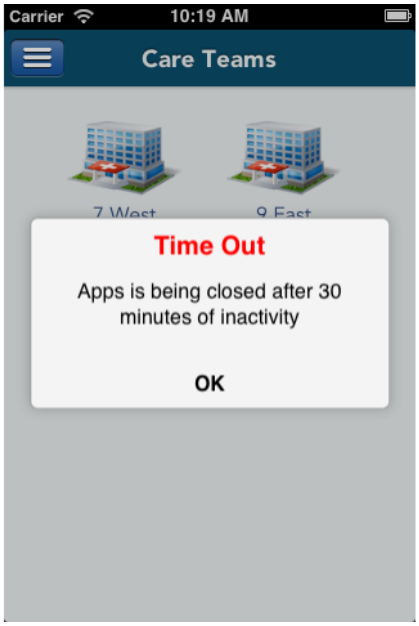
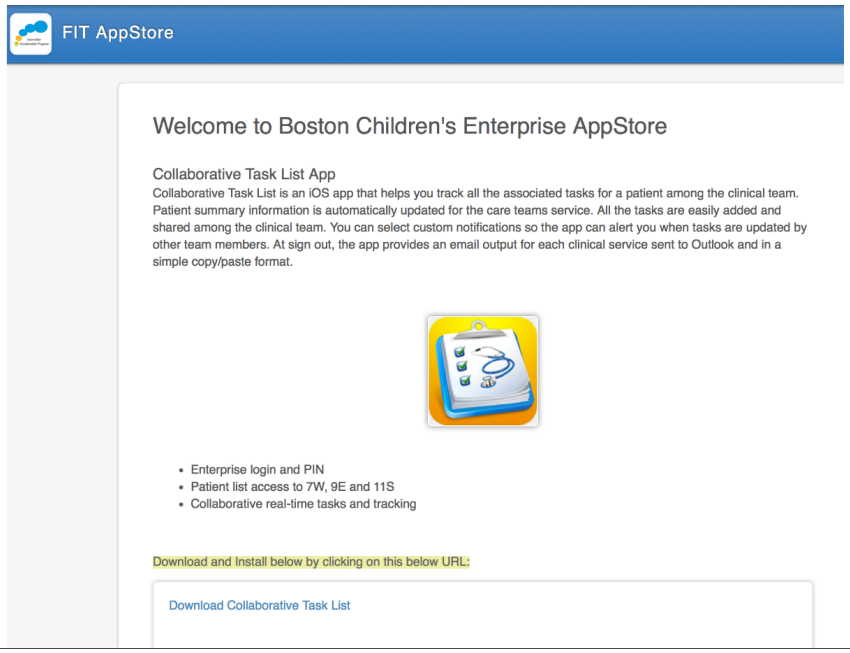


Figure 6. Boston Children's Hospital app store.



Implement Remote Wipe Out Functionality

Because TaskList does not store any data locally on a device and uses no-cache, the functionality that is able to remotely wipe out the device was not required. In the future, when many departments join the pilot, the data get bigger and more time is needed to load the data from server. Consequently, storing some of the data locally on the device and using on-memory cache and implementing remote wipe out functionality will be mandatory.

Implement Ability to Disconnect and Block a User Anytime

In the TaskList project, as residents leave the organization or no longer have access privileges to the app, their credential must be deleted. We built this functionality by creating a dynamic user table so that an administrator is able to manage user access status.

Discussion

Pricipal Findings

The benefits of using mobile devices in a hospital continue to be recognized as a growing necessity for the future of health care delivery. A recent study [30] found that 60% of physicians reported avoiding at least one adverse drug error per week by using information found on mobile apps. In the same survey, physicians also reported saving time by using smartphone medical apps, with one in two stating they saved 20 minutes or more daily. For a busy primary care physician, that could mean the ability to see two to four more patients each day. Still, the widespread use of mobile apps and devices that are fully

integrated into a comprehensive hospital information system or EMR remains a work in progress.

As a response to the aforementioned situation, we developed the guideline to build an app that complies with BYOD concerns and policies in a health care organization. The guideline helps both developers and security administrators balance between maximizing the use of personal devices in hospital settings and minimizing the security risk of BYOD with PHI. Using the guideline, we successfully implemented a mobile, collaborative, and real-time app called TaskList and piloted the app in a busy inpatient ward in a pediatric hospital. During the development and deployment processes, we also gained valuable knowledge and experience to build future apps that require similar robust security measures. Even though this manuscript focuses on custom developed apps for BYODs, this guideline is also relevant for vendors wanting to deploy any apps running on hospital supplied devices or BYODs.

Finally, through the application of the guideline to developing TaskList, we learned that there is no single solution that will solve all the BYOD issues in health care organizations, but a combination of legal policy, proper administrative procedure supported by advance technologies such as MDM apps, education, advance security detection, and ensuring all apps comply with established BYOD guidelines can help mitigate multiple security concerns.

Conclusions

This was our first initiative and is a preliminary approach to implement BYOD in BCH; thus, we will continue to investigate and analyze how to best integrate personal devices into the BCH environment. This paper demonstrates one example given the BYOD technologies at BCH in 2014 and we are aware that as the technologies advance so will the custom app development approach with BYOD. We expect that as the BYOD needs continue to grow within health care organizations, more apps will adhere to security standards that protect medical information. Until there are industry-accepted guidelines we will use this BCH BYOD guideline to inform our enterprise mobile development design approach. At the same time, we will keep it updated to ensure the guideline meets the latest technology and research standards.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

AES: advanced encryption standard
APNS: Apple push notification system
BA: business associate
BAA: business associate agreement
BCH: Boston Children's Hospital
BYOD: bring-your-own-device
EMR: electronic medical record
GCM: Google Cloud Messaging

HIPAA: Health Insurance Portability and Accountability Act
HITECH: Health Information Technology for Clinical Health Act
iOS: Apple operating system
ISD: information services department
IT: information technology
LAN: local area network
MDM: mobile device management
OTA: over-the-air
PHI: protected health information
PIN: personal identification number
RBAC: role-based access control
SSL: secure sockets layer
VPN: virtual private networks

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Original Paper

Smartphone Applications to Support Tuberculosis Prevention and Treatment: Review and Evaluation

Sarah J Iribarren[1], RN, PhD; Rebecca Schnall[1], RN, MPH, PhD; Patricia W Stone[1], RN, PhD; Alex Carballo-Diéguez[2], PhD

[1]Columbia University, School of Nursing, New York, NY, United States

[2]New York State Psychiatric Institute and Columbia University, Department of Psychiatry, New York, NY, United States

Corresponding Author:
Sarah J Iribarren, RN, PhD
Columbia University
School of Nursing
617 West 168th Street
New York, NY
United States
Phone: 1 212 342 3754
Fax: 1 212 305 0722
Email: si2277@columbia.edu

Abstract

Background: Tuberculosis (TB) remains a major global health problem and is the leading killer due to a single infectious disease. Mobile health (mHealth)–based tools such as smartphone apps have been suggested as tools to support TB control efforts (eg, identification, contact tracing, case management including patient support).

Objective: The purpose of this review was to identify and assess the functionalities of mobile apps focused on prevention and treatment of TB.

Methods: We searched 3 online mobile app stores. Apps were included if they were focused on TB and were in English, Spanish, or Portuguese. For each included app, 11 functionalities were assessed (eg, inform, instruct, record), and searches were conducted to identify peer-review publications of rigorous testing of the available apps.

Results: A total of 1332 potentially relevant apps were identified, with 24 meeting our inclusion criteria. All of the apps were free to download, but 7 required login and password and were developed for specific clinics, regional sites, or research studies. Targeted users were mainly clinicians (n=17); few (n=4) apps were patient focused. Most apps (n=17) had 4 or fewer functions out of 11 (range 1-6). The most common functionalities were inform and record (n=15). Although a number of apps were identified with various functionalities to support TB efforts, some had issues such as incorrect spelling and grammar, inconsistent responses to data entry, problems with crashing, or links to features that had no data. Of more concern, some apps provided potentially harmful information to patients, such as links to natural remedies for TB and natural healers. One-third of the apps (8/24) had not been updated for more than a year and may no longer be supported. Peer-reviewed publications were identified for only two of the included apps. In the gray literature (not found in the app stores), three TB-related apps were identified as in progress, being launched, or tested.

Conclusions: Apps identified for TB prevention and treatment had minimal functionality, primarily targeted frontline health care workers, and focused on TB information (eg, general information, guidelines, and news) or data collection (eg, replace paper-based notification or tracking). Few apps were developed for use by patients and none were developed to support TB patient involvement and management in their care (eg, follow-up alerts/reminders, side effects monitoring) or improve interaction with their health care providers, limiting the potential of these apps to facilitate patient-centered care. Our evaluation shows that more refined work is needed to be done in the area of apps to support patients with active TB. Involving TB patients in treatment in the design of these apps is recommended.

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KEYWORDS

mobile apps; mobile health; tuberculosis; review

Introduction

Tuberculosis (TB) remains a major global health problem and is the leading killer due to a single infectious disease. The World Health Organization (WHO) estimates that one-third of the world population harbors latent TB infections, 14.1 million people have active cases, 9 million are newly diagnosed per year, and 1.5 million deaths are attributable to TB annually [1-3]. This death toll equals 2% of global mortality, yet it is a disease for which a cure has existed for 70 years. Given that most deaths from TB are preventable, this death toll is recognized by WHO as unacceptably high [1].

A number of factors contribute to the persistence of TB and its high mortality rate. For example, factors that have been identified as impacting TB medication adherence include length of treatment course, complex regimens, medication side effects, poor access to health care services, poor communication with providers, lack of social support, negative perceptions, and stigma and discrimination [4]. Directly observed therapy (DOT), where a trained health care worker or treatment supporter observes medication ingestion daily, is a WHO-recommended strategy to provide patient support and assure drug adherence for TB treatment. However, there are challenges to implementing DOT in many settings [5]. For instance, DOT is labor-intensive, transportation-dependent, and often inconvenient; therefore, in some regions TB treatment is offered by self-administration when attention from health care workers is unavailable, costly, or difficult to access due to geographic distances [6,7]. No matter how the treatment is given, heightening patients' involvement in their own care; improving communication between patients and health care teams; and providing flexible patient-centered care, education, and support to patients during treatment are recommended to increase TB medication adherence [4,7].

There has been a rapid development of computers and information technology in all aspects of life including health care over the past 15 years [8]; one type of health care information technology development is mobile health (mHealth). Smartphone apps are reported to be ideal platforms for improving health outcomes because of their popularity, connectivity, and sophistication [9]. Increasingly, apps can support added functionalities beyond, for example, text messaging and have the potential for real-time data collection, graphic feedback, interactivity, and links to social functionalities. Apps are being developed as tools to support multiple aspects of health care, including prevention, diagnosis, data collection, treatment adherence monitoring, and disease surveillance. Apps have the potential to support TB prevention and treatment efforts by supporting health care providers in diagnosing TB, monitoring patient progress, and providing support to patients to successfully complete treatment [6].

In the past few years, the number of health-related apps available to consumers has more than doubled for the two leading platforms, iOS and Android [10]. A study published in 2015 by the IMS Institute for Health care Informatics identified more than 165,000 health-related apps [11] compared to about 40,000 in its 2013 report [12]. While there is a large literature base on human-computer interaction in many areas [13-15], the methods for review and assessment of health-related apps are evolving. Prior reviews report systematic methods for conducting searches in the literature and app stores to describe the breadth of apps available [16,17], while others have added detailed identification of characteristics and primary purpose of apps [18]. Shen et al [19] and Bender et al [20] developed their own app characteristic coding schemes to meet the needs of their review focus that included functionality criteria assessment such as media type, user interface, and inclusion of tools to identify disease before symptom or signs. Previously, we have used the criteria proposed by the Institute for Healthcare Informatics specifically to assess app functionalities [12]. Reviews exist for identifying apps to support treatment of chronic diseases such as diabetes and [17] chronic pain [16,18] as well as for the prevention, detection, and management of cancer and [20] depression [19]. We have conducted prior reviews assessing the prevention of infectious diseases such as health care-associated infection prevention [21] and HIV [22]. However, no studies have assessed available apps to support TB prevention or treatment. To fill this gap, we conducted this systematic review to identify the TB prevention and/or treatment support-related apps available, report on their characteristics, and assess their functionalities. Our objectives were to (1) detect the number of TB-related apps available in the main app stores, (2) describe their characteristics, (3) evaluate their range of functionalities, (4) identify any rigorous testing of the available apps, and (5) scan the gray literature to identify if other TB-related apps are in progress.

Methods

Overview

Methods to identify, evaluate, and report findings for this study were guided by the Quality and Risk of Bias Checklist for Studies that Review Smartphone Applications [23] and the app functionality categories described in the Institute for Healthcare Informatics report [12]. The checklist comprises 8 criteria for evaluating and reporting the quality of smartphone health-related apps (eg, data collection time frame, clearly described app search strategy, concise description of the app appraisal methods). This checklist helped guide the search strategy and data characteristic extraction form development and ensure completeness of reporting of the results. The adapted app appraisal method, based on the app functionality categories from the Institute for Healthcare Informatics report, is described and defined below (see Table 1) [12].

Search Strategy and App Selection

We conducted searches in 3 mobile app stores in the United States during June 2015: iTunes App Store, Google Play Store, and Amazon Appstore. We used the search terms *tuberculosis*, *TB*, *phthisis*, and *tuberculose*in each of the app stores. Apps were included if they focused on TB control efforts (eg, patient support, health care provider management, TB awareness) and excluded if they were not dedicated to TB efforts (eg, focused on other infectious diseases were games or unrelated) and not in English, Spanish, or Portuguese.

Two team members, SI and LO, independently reviewed titles, full marketing descriptions, and screenshots of the potential apps for relevance and inclusion and discussed discrepancies until consensus was reached. All apps not meeting inclusion criteria were excluded. The list was then reviewed for duplicate apps identified from multiple searches and terms and "lite" or demo versions of apps to produce the final list of unique apps (see Figure 1 flowchart).

Figure 1. Flowchart.

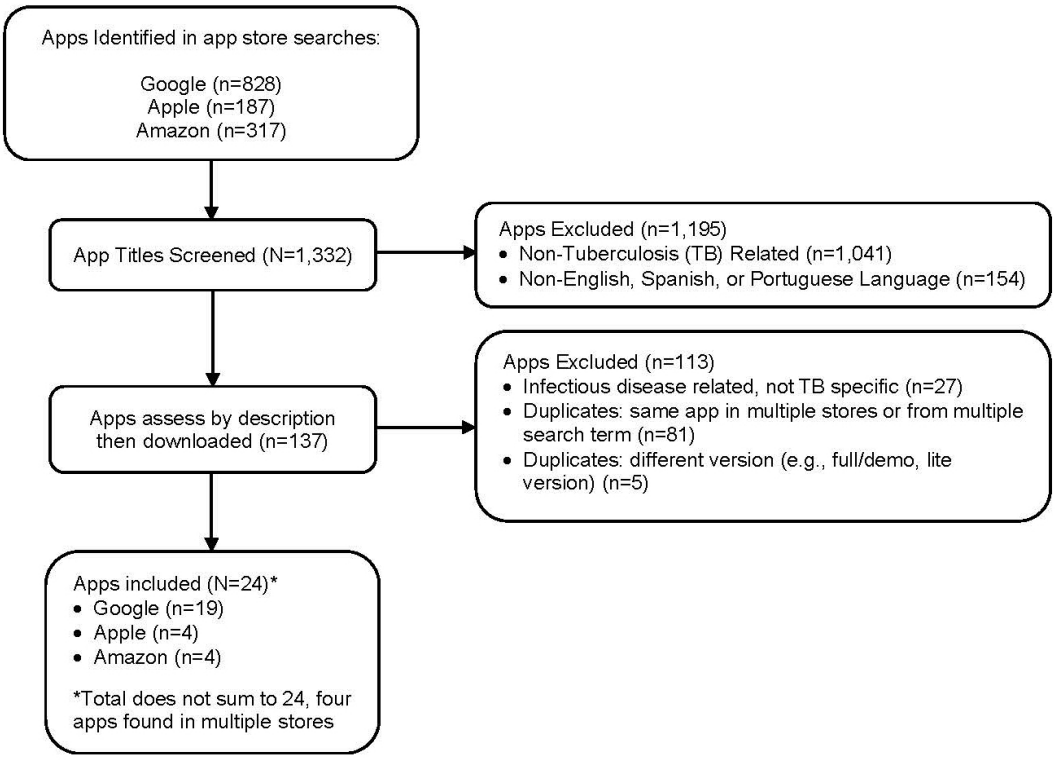


Figure 1. Screening process flowchart

Data Abstraction and App Functional Appraisal

Each eligible app was downloaded for functional appraisal. Emails were sent to listed company contacts for each of the apps requiring login and password to enter the full app content. We provided the purpose of this study and requested a test code, password, or further information about the app's functionalities.

A data abstraction form (available upon request) was developed based on the app functionality criteria from the Institute for Healthcare Informatics report [12] and a prior app evaluation data abstraction process [21]. Each app was characterized for store availability (eg, Apple, Amazon), country developed, target end-users, cost to download, number of downloads, rating and number of reviewers contributing to the rating, date of last update, primary purpose, and any specific issues or features of apps (eg, audio function to read text, language options). The app functionalities were appraised based on the 7 functionality criteria and 4 functional subcategories (Table 1). Each app was assessed for having or not having each of the 11 functionalities and given a functionality score (0-11).

Table 1. App evaluation criteria.

Functionality	Definition
Inform	Provide information; can be in a variety of formats such as text, photo, or video
Instruct	Provide instructions to the user (eg, specific steps to take for TB test or diagnosis)
Record	Capture user-entered data and record functional subcategories • Collect: enter and store health data on individual phone • Share: transmit health data (eg, upload, transfer, email) • Evaluate: evaluate the entered data • Intervene: send alerts based on the data collected or propose behavioral interventions or changes (eg, alert to treatment provider regarding treatment adherence, alert user for TB dosage due)
Display	Display user-entered data graphically and provide an output (eg, report, medication log, contact screening results, search results)
Guide	Provide guidance based on user-entered information (eg, patient TB risk factor screening and recommendations for testing, medication dosage based on entered data - weight/age). Having the function to enter search terms to obtain information or diagnostic criteria was not considered a guide functionality
Remind/alert	Provide reminders to the user (eg, medication, follow-up appointments)
Communicate	Facilitate communication between providers, patients, consumers, caregivers, and medication administrators or provide links to social networks (eg, Facebook, email)

Results

Descriptive Characteristics

Search queries yielded 1332 potentially relevant apps, of which 24 were included in our review. Most of the apps were excluded because they were not TB-related. See Figure 1 flowchart for selection process and categories for exclusion. Multimedia Appendix 1 provides the full list of the included apps and their characteristics. All of the apps were free to download; however 7 were developed for specific settings (eg, countries and/or clinical or research sites) and had restricted access requiring a login and password. The target end-users for most apps (n=17) were health care providers (eg, frontline health care worker, clinician, or lab technician) while a few (n=4) were patient-focused or could be used by patients and providers (n=3). A total of 13 apps were rated by 2 to 40 reviewers, and the mean rating was 4.4 (range 3.7-5, SD 0.5) on a scale of 1-5. Of the 18 apps with a reported range of downloads, 11 had been downloaded less than 500 times.

Functionality

Multimedia Appendix 2 provides the included app functionalities and scores based on the 7 functionality criteria and 4 functional subcategories adapted from the Institute for Healthcare Informatics report. Most apps (n=17) had 4 or fewer functions out of 11 (range 1-6). The most common functionalities were inform and record (n=15). There were 6 apps with the functions to display, guide, remind/alert, or communicate. For those with the function to inform, the majority focused on providing information on TB diagnosis, treatment (eg, medication, regimen, and age considerations), and transmission. The 3 apps that had an alert/reminder function (eCompliance, eDetection, and MDR-TB MDR Clinic) were for health care workers to display reports of expected appointments or pending questionnaires needed during home visits. The function to communicate was restricted to access to a social media link such as Facebook page (Tuberculosis News, TB Proof) (Figure 2) or an email contact to report app problems (Explain TB, SNTC).

The Explain TB app provided information in audio form and in multiple languages (Figure 3). One app did not function once downloaded (GuiaTB) and another crashed when opening a form within the app (eMocha). Seven of the apps require logins and passwords to access full functionality (eCompliance [Kenya, Jubilant Bhartia], eDetection, MDR-TB MDR Clinic Application, MDR-TB PHC Application, Global Fund TB, MINE TB, and TB REACH 4–Kotri).

Of the apps with the functionality to record, most collected (n=11) and shared data (n=10) (eg, sync to database or email results). Only 3 apps, CAD4TB, FIND TB, and TB Mobile, had the subfunction to evaluate (eg, provided feedback based on the data entered).

Figure 2. Tuberculosis News, TB Proof.

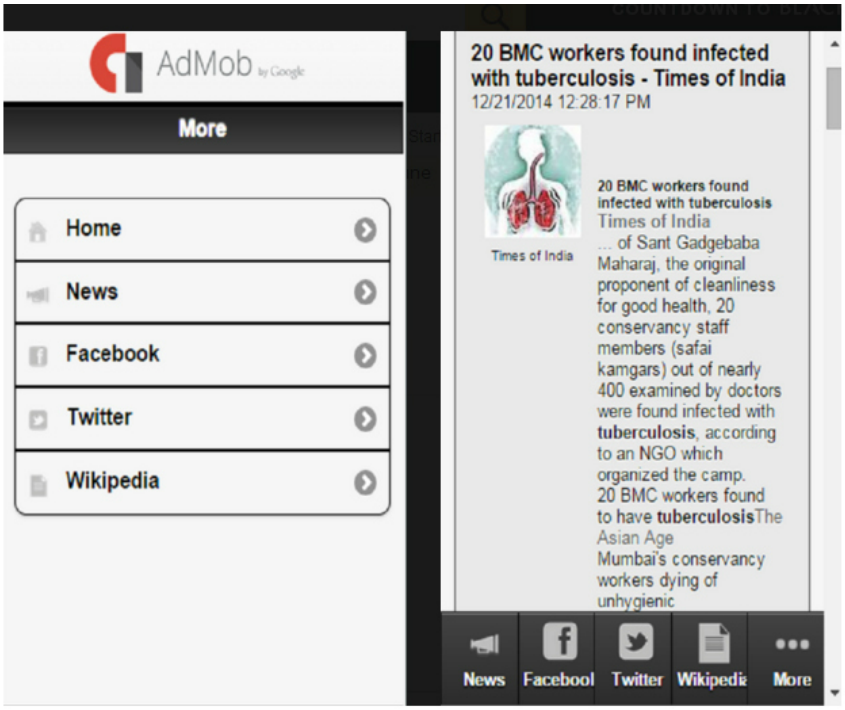


Figure 3. Explain TB.

Issues With Included Apps

Although a number of apps were identified as having various functionalities to support TB efforts, some had issues such as incorrect spelling and grammar, inconsistent responses to data entry, problems with crashing, or links to features that had no data.

For example, the Tuberculosis Symptoms Guide app (Figure 4) provides a TB syndrome screening form with 4 questions. The questions are as follows and are written verbatim from the app: Is the patient age 12 years? Is the patient HIV infected? Has the patient is in close contact with TB patients in home or at work? Does the patient has any symptoms? The recommended action provided after completing the screening questions is the same for all variations of responses (e.g., selecting “no” or “yes” to all questions). The response provided after answering the

questions is: “The patient has systomps of TB he/she must be tested as soon as possible by a health care professional to determine the TB. If he/she is detected TB then the family members should also be checked for TB.” In addition, this app has nonfunctioning Contact Us and FAQ tabs, lists only the names of 5 TB drugs without further information, and has many words misspelled (eg, nigtht sweats, systomps of TB).

The eMOCHA TB Detect app has tabs for TB symptom screening, education (TB lectures, courses, and library), and a disclaimer. As of July 2015, there are video lectures on prevention and risks for acquiring TB and two tables in the library; however, there were no courses available. When selecting the TB symptom screening form, the app crashes and closes. This app was last updated in 2013 and may no longer be supported. Similarly, GuiaTB could be downloaded but crashed upon opening; it appears to no longer function or be supported.

Of more concern were the apps that provided potentially harmful information. Tuberculosis (Amazon and Google) lists home remedy options or links to natural healers (Figures 5 and 6). For example, Tuberculosis (Google) provides links to information on medicinal herbs for treating TB and states “It seems like a cure all because it kills and neutralizes poisons;” these herbs are not consistent with evidence-based guidelines [24]. In addition, this app has many language options under settings but only the tabs and functions labels change language and not the content presented.

Figure 4. Tuberculosis Symptoms Guide.

Figure 5. Tuberculosis (Amazon). Home remedies.

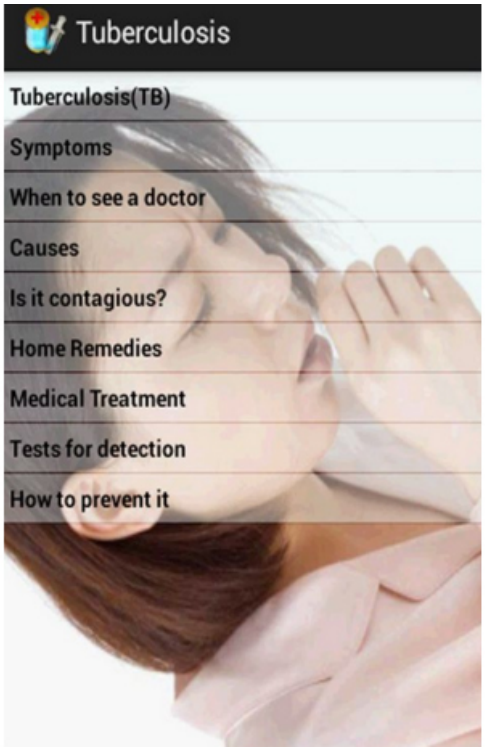
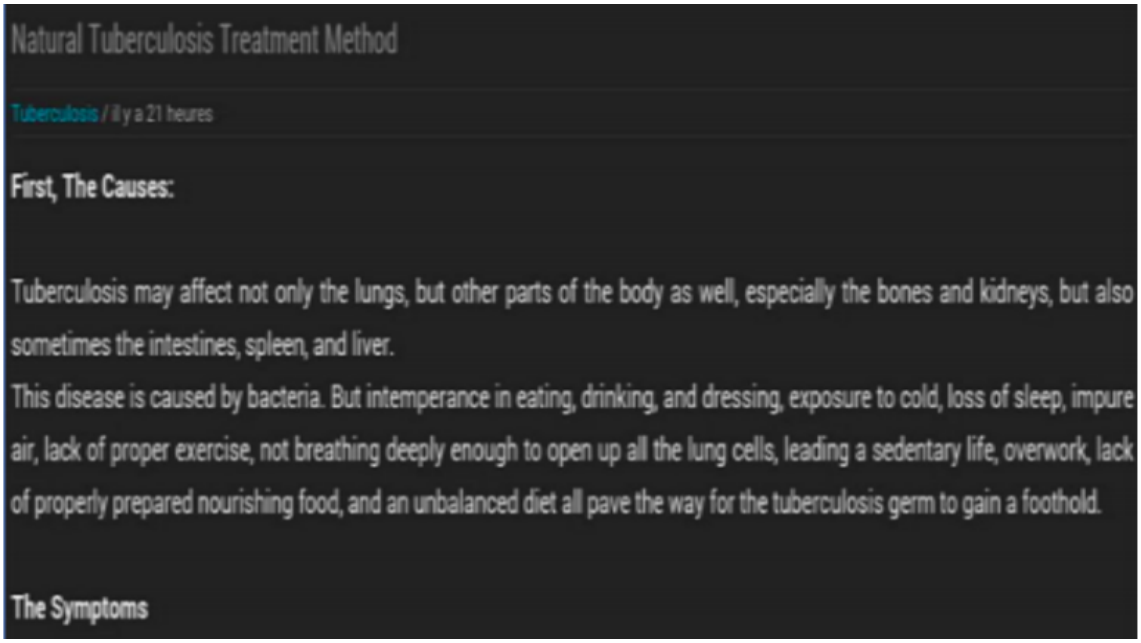


Figure 6. Tuberculosis (Google).



Formal Research Studies on TB-Related Apps

Peer-reviewed publications were identified for only two of the included apps. A formal research study was conducted to evaluate the app CAD4TB. Researchers conducted a cohort study to assess the app's sensitivity and specificity and found it helped accurately distinguish between the chest radiographs of culture-positive TB cases and controls [25]. Two publications described the development, features, and update of the TB Mobile app [26,27]. The researchers curated and prioritized data on molecules available in the Collaborative Drug Discovery database. App users can input molecular structures and search for potential targets to retrieve compounds known to be active. The authors state that the TB Mobile app has the potential to assist researchers in identifying targets for the development of antituberculosis drugs and purport that this mobile "cheminformatics" app could lower the barrier to drug discovery and promote collaboration among drug developers.

Another peer-reviewed publication reported on the design and piloting of a TB-related app not found in the app stores (Mobilize) [28]. Mobilize was developed to support health care workers in recording and tracking patients with multidrug-resistant TB. Last, the Centers for Disease Control and Prevention posted information on its webpage about the CDC LTBI app and its features [29] but there was no formal research study reported.

TB-Related Apps in the Gray Literature

Three TB-related apps were identified in the gray literature (not found in the app stores) as in progress, being launched, or in testing (DOTsync, Nikshay, and an unnamed app to assist in contact tracing). DOTsync is described as replacing paper-based systems and providing community workers with a tool to document DOT, monitor infection control and drug complications, track nutritional support, and conduct TB contact tracing [30]. The DOTsync app was developed by FHI 360's Control and Prevention of Tuberculosis project and the Myanmar Medical Association. Nikshay, launched by the government of India, aims to decrease the lengthy process of notifications, provide clinicians with a simpler case notification tool, and link the data to the Central Tuberculosis Division of the Ministry of Health and Family Welfare [31]. The aim of Nikshay is to increase enrollment in the national TB program, make the process easier for health care providers, and improve private sector reporting. The rollout started in March 2014 with email notification of the app being sent to general practitioners in Mumbai. The last app was unnamed but referred to in a poster abstract as an app developed to digitalize and automate contact tracing documentation in Botswana [32]. Preliminary results indicated that the app eliminated the need for manual data entry into the contact tracing database, required all form fields to be completed electronically prior to submission, automatically generated weekly and cumulative reports, and accurately captured the geographic coordinates of case homes. However, a final report was not identified in the literature.

Discussion

Principal Findings

The number of mHealth tools such as smartphone health-related apps has increased exponentially. As access to mobile phones, particularly smartphones and feature phones with the capacity to include mobile apps, continues to increase globally, the opportunity to harness their potential as a health-promoting tool grows as well. In conducting this research, we identified and evaluated functionalities of apps aimed at supporting TB prevention and treatment that were available in the leading mobile app stores. In addition, we identified apps reported in formal research studies and in the gray literature. Our review focuses on a specific, challenging disease and explores how apps available in the largest app stores might support TB prevention and treatment.

Almost all of the identified apps targeted health care providers as end-users, and the majority provided access to a broad

spectrum of TB information or tools aimed to support these workers in monitoring, detecting, and documenting visits. Similarly, the apps identified in the gray literature were reported to support frontline health care workers in documentation of cases, contact tracing, or management of patients. One app was designed to support those aiming to identify and develop new TB treatment development options.

There was a clear lack of apps specifically designed to provide treatment support and care management for patients or promote their involvement in their treatment. The apps targeting patients as end-users provided information on TB disease, symptoms, diagnostics, treatment, and transmission. None of the apps were developed for patients to help them with their treatment regimen (eg, reminders/alerts for follow-ups). Opportunities have been recognized for mHealth and mobile apps to be developed for chronic and infectious diseases such as HIV, but apps for TB control have not been developed to the same extent [6].

Few TB-related apps were found to have undergone formal research evaluation. The app Mobilize (identified in the literature but not available in any of the app stores) was reported as feasible and effective at decreasing adverse events and improving communication; however, the authors report that app uptake was poor, and health care workers cited forgetfulness and a belief that patients should take more responsibility for their own care as reasons for not consistently using the app [28]. The authors recommend exploring the motivations of health care workers and technological enhancements prior to scaling up mHealth tools.

A few apps presented information that misinformed patients about appropriate TB treatment options. Misinformation in health care apps has been problematic in other areas (eg, Acne App claimed that its mobile app could cure acne by emitting colored light from a cell phone). The US Federal Trade Commission sued the marketer of this app claiming it was unfair and deceptive and provided information potentially harmful to patients. However, with more than 100,000 health-related apps estimated to be in production, it is difficult to regulate and oversee app content. There is a real concern that app users can be misinformed-especially given the lack of regulations. The US Food and Drug Administration in 2013 indicated that it will be overseeing apps that capture and transfer patient data [33,34]; however, the rest of the app content is left up to the developers. Currently, there are no specific regulations to assure reliability/validity of information.

Another issue was the lack of current support and/or functionality for some apps despite availability from an app store. In a prior review of HIV apps, we also found apps that no longer functioned. On the positive side, the apps we assessed requiring log-ins and passwords use OpenMRS [35] (an open source enterprise electronic medical record system) are supporting interoperability across programs and likely addressing issues of data security and privacy as recommended in the Principles for Digital Development [36].

Implications

Existing mHealth tools can be improved and reused before new development is considered [36], but findings from this review suggest the need for development of apps for TB treatment for patients with the active disease. Apps that improve interaction with health care providers and support TB patient management and involvement in care appear to be lacking. Developing apps targeted at patients as end-users and involving TB patients in the design of these apps is recommended.

Although the checklist of 8 criteria for evaluating the quality and risk of bias for app evaluations is a helpful guide, its authors do not provide the criteria development process and indicate that the criteria were based on “simple facts and research transparency” [23]. In addition to the 8 criteria, we recommend specifying the last date updated because it is important to identify if the app continues to be managed/supported and is consistent with the most current clinical recommendations and guidelines. We also recommend including the country or setting for which the app was developed. The app characteristic evaluations have not been standardized. After we conducted our review, Stoyanov et al [37] published a mobile health app rating scale to classify and rate the quality of apps using 5 measures. In addition to app functionalities, the authors recommend review of patient engagement, aesthetics, and subjective quality. Our review assessed the range of downloads and user review ratings which may help inform the use and potential uptake. In addition, conducting searches outside of the app stores, such as in the gray literature, is helpful to identify apps under development or in production.

Limitations

This review has a number of limitations. First, app stores have limited advanced searching capabilities; therefore, we may have missed potentially eligible apps. However, we conducted broad searches with multiple terms to capture any apps meeting our broad inclusion criteria. In addition, based on our gray literature search findings, there appear to be other TB-related apps being trialed that have not been released to the public or in the app stores. We describe the apps in development that we identified, but there may be others that were missed.

Second, we attempted to capture apps in 3 languages (English, Spanish, and Portuguese). However, only one app was identified in Portuguese and none were in Spanish. It is possible that, depending on the country from which the searches were conducted, the apps available at the app stores may vary and apps in these languages were not made available outside of their region, but it would be surprising to limit access to apps available in Spanish within the United States. Also there were apps in other languages that we had to exclude because we were unable to assess them.

Third, not all app stores provide the same data, and not all apps could be fully accessed. For example, the Amazon Appstore does not provide information on range of downloads or date of last update (only release dates are provided) and none of the apps had been rated or reviewed at time of this review. To overcome the limitation on accessing apps, we sent email inquiries to all of the app contacts that required login and password but did not receive a response from any of them. Therefore, for 7 apps we conducted the functionality assessments using the online screenshot images and marketing descriptions. The online screenshots contained from 2 to 7 screenshots for

each app providing, in most cases, sufficient views to assess each functionality.

Last, although it was not the aim of our review, it is possible that there are apps for medication support that could provide medication management for patients on any treatment regimen, including TB. However, it is likely that they would not provide other TB-specific support such as information on infectivity, testing for close contacts, and common side effects of TB medications.

Comparison With Prior Work

Prior reviews of apps were not TB-specific, did not include a functionality score, or did not search for apps in the gray literature [20,21,38-42]. An evaluation of HIV apps included an audit of formative patient-identified app function needs and preferences. Shen et al [19] evaluated apps based on their store description to provide an overall description of depression apps. De la Vega and Miro [16] could find no articles published on apps they identified in app stores for pain management but did find articles published on apps not available in app stores. They identified a gap between the scientific and commercial faces of mHealth.

Conclusions

In our review, apps identified for TB efforts had minimal functionality, primarily targeted frontline health care workers, and focused on TB information (eg, general information, guidelines, and news) or data collection (eg, replace paper-based notification or tracking). Few apps were developed for use by patients and none were developed to support TB patient involvement and management in their care (eg, follow-up alerts/reminders, side effects monitoring) or to improve interaction with their health care providers, limiting the potential of these apps to facilitate patient-centered care. Given the complex challenges faced by patients with TB, there is a need for further app development targeting their needs. Our evaluation shows that more refined work is needed in this area. Involving TB patients in treatment in the design of these apps is recommended.

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Authors' Contributions

SI and RS contributed to research methods. All authors contributed to manuscript drafting. SI contributed to data collection and evaluation.

Conflicts of Interest

None declared

Multimedia Appendix 1

Characteristics of applications to support TB efforts.

[PDF File (Adobe PDF File), 104KB - mhealth_v4i2e25_app1.pdf]

Multimedia Appendix 2

App functionalities and scores.

[PDF File (Adobe PDF File), 192KB - mhealth_v4i2e25_app2.pdf]

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Abbreviations

DOT: directly observed therapy
mHealth: mobile health
TB: tuberculosis
WHO: World Health Organization

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Original Paper

Review and Analysis of Existing Mobile Phone Apps to Support Heart Failure Symptom Monitoring and Self-Care Management Using the Mobile Application Rating Scale (MARS)

Ruth M Masterson Creber[1], PhD, MSc, RN; Mathew S Maurer[2,3], MD; Meghan Reading[1], BSN, MPH, RN; Grenny Hiraldo[1]; Kathleen T Hickey[3], EdD, FNP, ANP, FAHA, FAAN; Sarah Iribarren[1], PhD, MPH, RN

[1]Columbia University, School of Nursing, New York, NY, United States

[2]College of Physicians & Surgeons, Columbia University, New York, NY, United States

[3]NewYork-Presbyterian/Columbia University Medical Center, Division of Cardiology, New York, NY, United States

Corresponding Author:
Ruth M Masterson Creber, PhD, MSc, RN
Columbia University
School of Nursing
617 W 168th St
New York, NY, 10032
United States
Phone: 1 2123050391
Fax: 1 2123056937
Email: rm3284@cumc.columbia.edu

Abstract

Background: Heart failure is the most common cause of hospital readmissions among Medicare beneficiaries and these hospitalizations are often driven by exacerbations in common heart failure symptoms. Patient collaboration with health care providers and decision making is a core component of increasing symptom monitoring and decreasing hospital use. Mobile phone apps offer a potentially cost-effective solution for symptom monitoring and self-care management at the point of need.

Objective: The purpose of this review of commercially available apps was to identify and assess the functionalities of patient-facing mobile health apps targeted toward supporting heart failure symptom monitoring and self-care management.

Methods: We searched 3 Web-based mobile app stores using multiple terms and combinations (eg, “heart failure,” “cardiology,” “heart failure and self-management”). Apps meeting inclusion criteria were evaluated using the Mobile Application Rating Scale (MARS), IMS Institute for Healthcare Informatics functionality scores, and Heart Failure Society of America (HFSA) guidelines for nonpharmacologic management. Apps were downloaded and assessed independently by 2-4 reviewers, interclass correlations between reviewers were calculated, and consensus was met by discussion.

Results: Of 3636 potentially relevant apps searched, 34 met inclusion criteria. Most apps were excluded because they were unrelated to heart failure, not in English or Spanish, or were games. Interrater reliability between reviewers was high. AskMD app had the highest average MARS total (4.9/5). More than half of the apps (23/34, 68%) had acceptable MARS scores (>3.0). Heart Failure Health Storylines (4.6) and AskMD (4.5) had the highest scores for behavior change. Factoring MARS, functionality, and HFSA guideline scores, the highest performing apps included Heart Failure Health Storylines, Symple, ContinuousCare Health App, WebMD, and AskMD. Peer-reviewed publications were identified for only 3 of the 34 apps.

Conclusions: This review suggests that few apps meet prespecified criteria for quality, content, or functionality, highlighting the need for further refinement and mapping to evidence-based guidelines and room for overall quality improvement in heart failure symptom monitoring and self-care related apps.

(JMIR Mhealth Uhealth 2016;4(2):e74) doi:10.2196/mhealth.5882

KEYWORDS

mobile apps; mobile health; heart failure; self-care; self-management; review; symptom assessment; nursing informatics

Introduction

Heart failure (HF) is a common, complex, and costly cardiovascular condition. Heart failure currently affects 5.7 million Americans [1], is the fastest growing cardiovascular condition in the United States [2], and the most common reason for hospitalization among older adults [3-6]. Worldwide, the prevalence of HF is estimated to be more than 23 million people [7]. The most common reason for HF-related hospitalizations is symptom exacerbations. Symptom changes are often insidious, making it difficult for patients to recognize and respond to changes early and resulting in need for hospital-based management of HF exacerbations. To reduce the societal and cost burden of HF, effective symptom management strategies are important for patients and also may help to reduce hospital admissions [8,9]. Major clinical guidelines recommend the inclusion of daily symptom monitoring as part of routine management of patients with HF [10].

With an uptake of mobile phone ownership among adults in the United States [11], there is growing opportunity to capitalize on the use of mobile phone technology to enhance the management of HF. Mobile phones are an optimal vehicle for housing mobile health (mHealth) apps for symptom monitoring because they are accessible continuously, portable, and convenient. Mobile health apps are reported to be an ideal platform for behavior change because of popularity, connectivity, and increased sophistication [12]. Apps can support added functionalities and have the potential for real-time data collection, graphic feedback, interactivity, and links to social functionalities [12]. In addition, apps have the potential to be useful for symptom management because they can include behavioral prompts, reminders, illness monitoring, and self-management programs that extend far beyond the clinic walls.

Currently, reviews of commercial mHealth apps exist to support patients undergoing bariatric surgery [13], those who are managing bipolar disorder [14], cancer [15], cardiovascular disorders [16], chronic pain [17,18], depression [19], diabetes [20], health care–associated infection prevention [21], human immunodeficiency virus [22,23], and schizophrenia [24]. A review has been conducted on published literature on mHealth apps for HF [25]; however, it did not include an evaluation of commercially available mHealth apps. To date no studies have assessed commercially available apps to support HF symptom monitoring and self-care. To address this gap, we conducted a thorough review of commercially available existing mobile apps focused specifically on self-management and symptom monitoring for patients with HF. Our objectives were to (1) identify HF-related apps available in the main app stores; (2) describe their characteristics; (3) identify if any of the available apps have been rigorously tested; and (4) rate the quality of the apps based on the Mobile Application Rating Scale (MARS) [26], functionality score from the IMS Institute for Healthcare Informatics report [27], and Heart Failure Society of America (HFSA) guidelines for nonpharmacologic management [10].

Methods

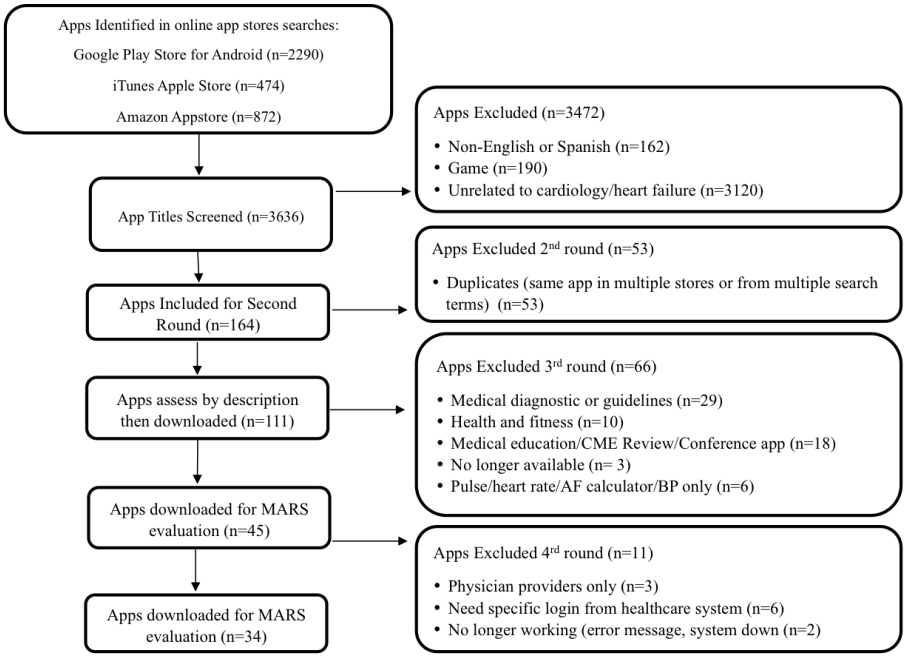
Systematic Search Criteria and Selection

In January 2016, we conducted a thorough review of mobile apps across 3 mobile app stores: Apple iTunes Store, Android Google Play store, and Amazon Appstore. The following search terms were included: “heart failure,” “cardiology,” “heart failure and self-management,” “heart failure and symptom management,” “heart failure and symptom monitoring,” “heart failure and self-care,” “cardiology and symptom management,” “cardiology and symptom monitoring,” “heart,” “symptom,” “symptom management,” “self-care,” and “self-care and heart.” Each term was searched in each of the 3 app stores listed.

Preliminary screening was conducted based on app titles, full marketing description, and screenshots of the potential apps for relevance and inclusion. Apps were excluded if they were games, unrelated to health, or not written in English or Spanish. The second round of exclusion criteria focused on removing (1) duplicate apps (those found in multiple stores or from multiple search terms), (2) highly similar versions of the same app (eg, “lite” or “pro” versions), (3) apps that are not patient-facing, (4) apps focused solely on health and fitness, (5) apps for continuing medical education or conference apps, and (6) apps that were no longer available (Figure 1). Team members reviewed the apps after each round of exclusion criteria were completed (almost 70% of the apps were rated by at least two reviewers). The remaining apps were downloaded, reviewed (iOS 9.2.1 on iPhone 6; iPad mini or Android phone), rated, and evaluated by 2 reviewers (GH and RMC).

A data extraction form was built using a Google Docs survey that included the full MARS scale, IMS Institute for Healthcare Informatics functionality scoring system, and 8 questions related to specific self-care behaviors recommended in the “Nonpharmacologic Management and Health Care Maintenance in Patients with Chronic Heart Failure” published by the HFSA [10].

Figure 1. Screening process flowchart.



Abbreviations: AF: atrial fibrillation; BP: blood pressure; CME: continuing medical education.

Measures or Rating Tool

We rated and ranked the apps based on 3 scores: (1) MARS quality score [26], (2) IMS Institute for Healthcare Informatics functionality score [27], and (3) consistency with HFSA guideline recommendations [10] with an additional question related to the number of self-care behaviors that the apps addressed. The MARS was used to rate app quality and includes 3 sections and a modifiable app-specific section: classification, quality, and satisfaction [26]. The classification section provides descriptive information about the apps. The objective app quality section includes 19 items divided into 4 scales: engagement, functionality, aesthetics, and information quality. The subjective quality section contains 4 items evaluating the user's overall satisfaction. MARS items are scored using a 5-point Likert scale (1-inadequate, 2-poor, 3-acceptable, 4-good, and 5-excellent). The final MARS scores include 4 subscale scores, a total mean score, subjective quality score, and an app-specific subscale that assesses perceived effect on the user's knowledge, attitudes, and intentions to change as well as likelihood of changing the identified targeted behaviors.

The IMS functionality score is based on 7 functionality criteria and 4 functional subcategories as described in detail in the IMS Institute for Healthcare Informatics report [27] (Table 1). Each app was assessed for having or not having 11 functionalities and given a functionality score (0-11) [27].

Table 1. IMS Institute for Healthcare Informatics functionality scoring criteria.

Functionality scoring criteria	Description
1. Inform	Provides information in a variety of formats (text, photo, video)
2. Instruct	Provides instructions to the user
3. Record	Capture user entered data
Collect data	Able to enter and store health data on individual phone
Share data	Able to transmit health data
Evaluate data	Able to evaluate the entered health data by patient and provider, provider and administrator, or patient and caregiver
Intervene	Able to send alerts based on the data collected or propose behavioral intervention or changes
4. Display	Graphically display user entered data/output user entered data
5. Guide	Provide guidance based on user entered information, and may further offer a diagnosis, or recommend a consultation with a physician/a course of treatment
6. Remind or Alert	Provide reminders to the user
7. Communicate	Provide communication with HCP[a]/patients and/or provide links to social networks

[a]HCP: health care provider.

Two functionality scores were used for this review because the functionality scores provide different types of information on app functionality. The MARS functionality score focuses on performance, ease of use, navigation, and gestural design of the app [26], whereas the IMS Institute for Healthcare Informatics functionality score focuses on scope of functions, including informing, instructing, recording, displaying, guiding, reminding, and communicating information [27].

Each of the apps was also evaluated for whether it included 8 specific self-care behaviors recommended by HFSA guidelines [10]. These behaviors included daily weighing, checking extremities for swelling, doing physical activity or exercise, eating a low-salt diet, taking daily medications, attending doctor's appointments, daily monitoring of HF symptoms, and actively responding to symptoms when they change, consistent with HFSA nonpharmacologic guidelines [10].

Data Analysis

Four reviewers (GH, RMC, MR, and SI) watched the accompanying MARS instructional videos for how to use the MARS scale. Each reviewer rated 4 randomly selected apps to evaluate interrater reliability. The interclass correlation coefficients (ICCs) were calculated between the 4 reviewers. On the basis of ICC guidelines by Shrout and Fleiss [28], we selected an individual consistency-of-agreement intraclass correlation (CA-ICC) for a two-way random-effects model. The assumptions of this model include that the variance of raters only adds noise to the mean estimate and that the mean rater error is zero. It also models both the effect of the individual rater as well as the average of the raters and assumes both are drawn randomly from a larger population [29].

Results

Descriptive Characteristics

Android Google Play, Apple iTunes, and Amazon Appstore searches identified 3636 potentially relevant apps, of which 34 met our final inclusion criteria. The flow diagram (Figure 1) provides an overview of the selection process and categories for exclusion. Most apps were excluded because they were unrelated to HF (n=3120), not available in English or Spanish (n=162), or were games (n=190).

Table 2 provides the full list of the included apps and their characteristics. Most apps were free to download (31/34, 91%) with costs up to US $4.99. Most of the apps have been updated within the last year (63%). The average consumer star rating across all of the apps was 3 out of 5 with a range of 0 to 5. The number of individual ratings ranged from 0 to more than 52,000. Most of the apps had been installed between 100 and 500 times, but WebMD and iTriage had been installed between 5 and 10 million times. Almost 50% of the apps included a privacy policy.

Table 2. Description of included apps.

Name	Star rating	Installs[a]	Version	Cost, US $	Platform	Privacy policy	IMS score[b]
ASCVD[c] Risk Estimator	3.5	N/R[d]	1.1	Free	Apple	No	6
AskMD	5	N/R	2.4.1	Free	Apple	No	9
BloodPressureDB	4.3	100-500K	5.64.0	Free	Google	Yes	7
Cardiograph	3.8	100-500K	3.2	Free	Google	Yes	5
Continuous Care Health App	3.9	100-500K	2.2.6	Free	Apple & Google	Yes	11
FAQs in Heart Failure	4.3	1-5K	1.2	Free	Google	No	2
Health Manager	3.5	N/R	2.1	$4.99	Apple	Yes	7
Healthy Ally	0	10-50	1.3.4	Free	Google	Yes	6
Healthy Heart	0	10-50	1.0.2	Free	Google	No	1
Healthy Heart Numbers	0	N/R	1	$2.99	Amazon	No	2
Heart Disease	3.3	500-1000	2.3.3	Free	Google & Amazon	No	1
Heart Disease & Symptoms	3.7	500-1000	1	Free	Google	No	0
Heart Failure Health Storylines	0	100-500	2.2.6	Free	Apple & Google	Yes	10
Heart Guide	0	100-500	1	Free	Google	Yes	4
Heartkeeper	4.7	1-5K	1.3	Free	Google	Yes	7
Heart Log	2	N/R	1.2	Free	Apple	No	5
Heart Services	3.8	100-500K	1.7.3	Free	Google	No	3
iTreat-Medical Dictionary	4.4	5-10K	1	Free	Apple & Google	Yes	4
iTriage	4.5	5-10 million	5.26	Free	Apple & Google	Yes	9
mediSOS	5	100-500	1.12	Free	Google	Yes	4
Miniatlas Hypertension	0	N/R	4	$1.99	Apple	No	3
My Cardiologist	5	100-500	1	Free	Google	No	2
My Health Tracker	2.7	N/R	1	Free	Amazon	No	3
My Heart Rate Monitor & Pulse Rate	4	N/R	1.3	Free	Apple	No	5
MyHeartApp	5	N/R	1.5	Free	Apple	No	4
Pulse Pro	3	N/R	1.2.4	Free	Apple	Yes	4
REKA	4.6	500-1000	2.0.5	Free	Google	Yes	3
SelfCare-My Health Record (MHR)	0	N/A[d]	1	Free	Apple	No	5
Symple	4.5	N/R	2.0.6	Free	Apple	Yes	11
Track your Heart Failure Zone	0	N/R	1	$1.99	Amazon	No	2
Urgent Care 24/7	4	N/R	1.1	Free	Apple	Yes	9
URI Life	4.6	1-5K	1	Free	Google	Yes	6
WebMD	4.5	5-10 million	5.9.3	Free	Apple & Google	No	11
WOW ME 2000mg	4	100-500	1.1	Free	Apple & Google	No	7

[a]Data on number of installs were only available in Google Play.

[b]The IMS score is the IMS Institute for Healthcare Informatics functionality score ranging from 0-11.

[c]ASCVD: atherosclerotic cardiovascular disease

[d]N/R: not recorded.

[d]N/A: not applicable.

MARS App Quality Scores

Table 3 presents the 4 subscale scores (engagement, functionality, aesthetics, and information), overall quality score, subjective quality score (satisfaction), and app-specific health behavior score from the MARS. It was not possible to rate item 19, because a PubMed search identified only 3 efficacy studies among the 34 apps. More than 2/3 of the apps were evaluated by 2 or more expert MARS raters, and there was excellent interrater reliability (two-way mixed CA-ICC=.93, 95% CI: 0.68-0.99). Of the 4 subscales, functionality had the highest score and median engagement had the lowest (2.9).

The median overall MARS score was 3.4 out of 5, and 68% (23/34) had a minimum acceptability score of 3.0. Overall, the AskMD app had the highest average MARS total (4.9) followed by WebMD (4.4), Symple (4.3), Heart Failure Health Storylines (4.1), and ContinuousCare Health App (4.0). Heart Failure Health Storylines (4.6) and AskMD (4.5) had the highest scores for behavior change.

Table 3. Mobile Application Rating Scale scores.

Name	Engage	Function	Aesthetics	Information	Satisfaction	Behavior change	Overall
AskMD	5.0	5.0	5.0	4.6	4.3	4.5	4.9
WebMD	4.1	4.9	4.5	4.2	3.6	2.8	4.4
Symple	4.1	4.5	4.5	3.9	3.8	4.1	4.3
Heart Failure Health Storylines	4.3	4.2	3.3	4.5	3.9	4.6	4.1
Continuous Care Health App	4.1	4.6	3.7	3.7	4.1	3.8	4.0
Heart Keeper	4.0	4.0	4.0	3.5	3.0	4.2	3.9
mediSOS	3.8	4.3	3.7	3.8	3.5	3.5	3.9
Heart Log	4.5	4.5	3.0	3.2	2.0	2.8	3.8
Healthy Ally	3.5	4.0	4.0	3.5	2.5	3.0	3.8
MyHeartApp	3.9	3.5	4.3	3.3	3.1	4.1	3.7
Urgent Care 24/7	2.5	4.5	3.8	4.0	4.1	3.6	3.7
ASCVD Risk Estimator	3.0	3.8	3.2	4.3	2.3	3.2	3.6
FAQs in Heart Failure	2.5	4.3	3.7	3.8	2.1	2.8	3.6
Miniatlas Hypertension	2.1	4.5	3.7	3.8	1.9	2.5	3.5
iTriage	3.1	3.9	3.5	3.5	3.0	3.7	3.5
REKA	3.3	3.5	4.0	3.2	2.8	3.0	3.5
Heart Guide	2.5	3.5	4.7	3.0	2.0	4.0	3.4
SelfCare-MHR	2.8	4.3	3.3	3.3	2.3	3.0	3.4
WOW ME 2000mg	2.9	4.6	3.0	2.9	2.6	3.3	3.4
Cardiograph	2.9	3.8	3.5	2.8	1.8	3.8	3.2
BloodPressureDB	3.3	3.5	3.0	3.1	2.6	3.3	3.2
URI Life	3.5	3.0	3.0	3.0	2.3	3.0	3.1
Pulse Pro	2.1	3.4	3.2	3.1	2.1	2.5	2.9
Heart Disease & Symptoms	1.0	3.8	2.3	3.7	1.0	2.0	2.7
Health Manager	2.8	2.5	2.5	2.4	1.5	3.3	2.5
Heart Services	3.3	1.8	3.0	2.1	1.0	2.0	2.5
My Heart Rate Monitor & Pulse Rate	2.3	2.4	2.8	2.0	1.8	2.3	2.4
Heart Disease	1.2	4.1	1.6	2.2	1.3	1.5	2.2
My Cardiologist	1.3	1.3	3.0	2.3	1.0	1.3	2.0
iTreat-Medical Dictionary	2.0	1.5	2.3	1.2	1.0	1.0	1.7
My Health Tracker	1.5	2.0	1.0	2.3	1.0	1.3	1.7
Track your Heart Failure Zone	1.0	1.0	1.3	1.8	1.0	0.8	1.3
Healthy Heart Numbers	1.0	1.8	1.3	1.0	1.0	1.0	1.3
Healthy Heart	1.0	1.0	1.3	2.2	1.0	2.0	0.8

Functionality

Figure 2 illustrates the functionalities of the apps and highlights that nearly all had a record function (29/34, 85%). The median number of functionalities was 5 and the majority of apps (66%) had less than 7. Twenty-four apps had the option to display, 18 to inform, 16 to communicate, 15 to instruct, 15 to guide, and 10 to remind/alert. Three apps had a total of 11 functionalities (WebMD, Symple, and ContinuousCare Health App) followed by Heart Failure Health Storylines, which had 10 functionalities.

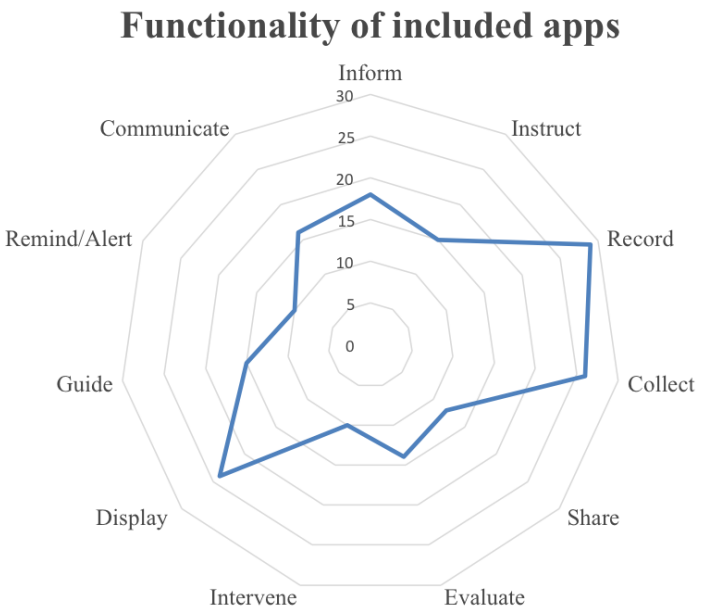
Of the 29 apps that had the function to record, 26 could collect data, 12 could share the data, and 10 had the function to intervene. Examples of data that were collected using these apps include medications, symptoms, daily moods, daily vital signs, and physical activity.

Heart Failure Health Storylines and WebMD have the ability to sync (collect) with a wide variety of fitness devices, apps, and even some scales. Many of the apps sync with the Apple Health app for iPhone users. Examples of apps that included the option to share data included Heart Failure Health Storylines and ContinuousCare Health App. In Heart Failure Health Storylines, the user has the option to share or communicate each feature with certain "circles of support" to which the user can add friends and family through email or keep the data private, including symptoms, vital signs, moods, and journal entries. Heart Failure Health Storylines does not have an option to share data using a message feature.

ContinuousCare Health App has a newsfeed feature that includes health-related articles and a customizable user profile. ContinuousCare Health App also includes the option for real-time consultation with a licensed health care provider, as well as a "Doctor Virtual Practice" that allows the user to invite his or her provider to virtually track data and communicate with the user in the app itself.

Symple offers a data exportation (share feature) that allows the user to back up data recorded in the app to a personal email or a spreadsheet app. In Symple users can also share an overview of current symptoms with their doctor. This document saves a PDF attachment and can then be sent over email. In WebMD the user can share health data and providers can respond and share education materials through this feature, which is password-protected.

Figure 2. Functionality of included apps based on IMS Institute for Healthcare Informatics functionality scores.



Heart Failure Society of America Guidelines

Table 4 includes the 8 HF-specific self-care behaviors evaluated. The most commonly addressed was daily monitoring of symptoms (21/34, 62%), followed by responding to symptoms (16/34, 47%), taking daily medications (13/34, 38%), following a low-salt diet (10/34, 29%), going to provider appointments (6/34, 18%), doing exercise (7/34, 21%), daily weighing (7/34, 21%), and checking extremities for swelling (8/34, 24%). The app that addressed all of these self-care behaviors was Heart Failure Health Storylines, which was developed in collaboration with the HFSA.

Table 4. Heart Failure Society of America–recommended nonpharmacologic management behaviors included in the apps.

Name	Weight	Check swelling	Physical activity	Diet	Medication	MD appointment	Monitor symptoms	Symptom response	Total score[a]
Heart Failure Health Storylines	✓	✓	✓	✓	✓	✓	✓	✓	8
WOW ME 2000mg	✓	✓	✓	✓	✓		✓	✓	7
WebMD	✓	✓	✓	✓	✓		✓	✓	7
ContinuousCare Health App	✓		✓	✓	✓		✓	✓	6
iTriage		✓		✓	✓		✓	✓	5
URI Life			✓	✓	✓	✓	✓		5
AskMD	✓	✓		✓	✓				4
Health Manager	✓				✓		✓	✓	4
Heart Keeper			✓		✓	✓	✓		4
MyHeartApp	✓			✓			✓	✓	4
Urgent Care 24/7		✓		✓			✓	✓	4
ASCVD Risk Estimator		✓	✓	✓					3
BloodPressureDB					✓		✓	✓	3
Symple		✓					✓	✓	3
Cardiograph							✓	✓	2
Heart Log						✓	✓		2
mediSOS					✓			✓	2
My Heart Rate Monitor & Pulse Rate							✓	✓	2
Pulse Pro							✓	✓	2
REKA							✓	✓	2
SelfCare-MHR							✓	✓	2
Healthy Ally							✓		1
Healthy Heart Numbers					✓				1
Heart Disease & Symptoms						✓			1
Heart Guide							✓		1
Miniatlas Hypertension					✓				1
My Cardiologist						✓			1
My Health Tracker							✓		1

[a]Apps that scored a zero did not include any symptom monitoring or self-care behaviors and were removed from the table.

Overall App Quality

Factoring in the MARS, IMS Institute for Healthcare Informatics functionality, and HFSA guideline scores, the highest performing apps included Heart Failure Health Storylines, Symple, ContinuousCare Health App, WebMD, and AskMD.

A PubMed search of the apps in this review found that only 3 apps have been evaluated and published in peer-reviewed journals [30-32].

Discussion

This study is the first to comprehensively review commercially available mobile apps for HF symptom monitoring and self-care and independently evaluate their quality using validated multiple rating scales, including the MARS expert rating scale, IMS Institute for Healthcare Informatics functionality scale, and HFSA guidelines for nonpharmacologic management. The most common functionality among the 34 apps reviewed was being able to record information, typically syncing data from other sources. Few apps provided any guidance in response to reported input, reminders or alerts about medications or symptom tracking, or the ability to communicate with providers.

The 2 apps that provided the most options for symptom tracking included Heart Failure Health Storylines and Symple (Figure 3). Heart Failure Health Storylines includes the feature of being able to track multiple symptoms simultaneously to allow the user to detect potential correlations between symptoms and time periods. Users can record symptom severity, moods, vital signs,

and medications and the data are displayed using a color-coding scheme and weekly calendar format. The vital sign data are also displayed in a line graph to show daily fluctuations.

In Symple, users enter symptoms by calendar date and select the time of day and severity of each symptom (none, mild, moderate, difficult, severe) from a color-coded graphic (Figure 3). Symptoms are displayed using blocks with the same color-coding scheme in a weekly calendar format. Users can choose to view symptoms from one time of day (eg, every morning this week) or the entire day. One drawback of this feature is that it only allows viewing of one symptom at a time; multiple symptoms cannot be plotted on the same calendar.

Despite the pressing need that patients with HF have for better symptom and self-monitoring tools, most mHealth apps are designed to support healthy living rather than chronic disease management. Many apps focused on helping patients find a diagnosis for their symptoms (ie, AskMD and WebMD). Some of the apps supported self-care maintenance in terms of recording daily health behaviors or including reminders about taking medication, but were very limited with self-care management behaviors including more advanced symptom monitoring, tracking, and evaluation of whether specific behaviors improved health outcomes.

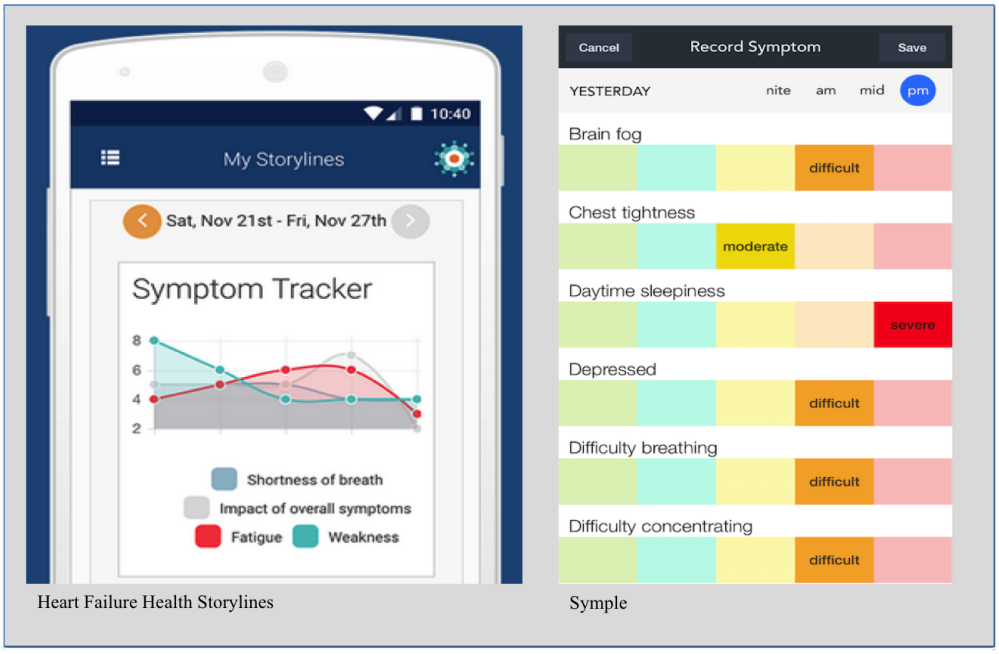
A total of 3 peer-reviewed articles evaluated 3 of the Web-based apps. The first article was a brief review on the development and future directions of the ASCVD Risk Estimator app [30]. The second article was an evaluation of the Heartkeeper app using Google app usability standards (completed by the authors) and a quality of experience survey completed by 24 users who were recruited through the app itself [31]. This review found the app to be generally compliant with Google's standards; it had mixed feedback on the quality of experience. The third article was a 4-month trial of the iTreat app in the hospital setting among 39 junior doctors in the United Kingdom [32]. Although participants reported some positive outcomes from using the app, the study highlighted many barriers to the use of mobile phones in the hospital setting [32].

Many apps are being used with minimal knowledge of their functionality and ability to integrate data into health care systems [27], let alone efficacy for improving patient or clinical outcomes. The lack of efficacy testing in clinical trials is one of the biggest barriers to adoption of mHealth apps. Health care providers are reticent to prescribe apps without evidence of their benefit, guidelines regarding use in clinical practice, and confidence in the privacy and security of personal health information that is both stored and transmitted [27]. These barriers are the major reasons why apps need to undergo rigorous clinical trial testing before they can be fully integrated into clinical care.

One good example of an mHealth app with demonstrated effectiveness for managing diabetes is BlueStar from WellDoc Diabetes Management. This app has been evaluated in a clinical trial and has demonstrated effectiveness for supporting diabetes management [33]; however, it is only accessible for patients with diabetes who have a prescription from their health care provider and it is not otherwise available to the public.

These findings suggest that apps have not yet been readily adopted into routine clinical management and need further development to support comprehensive symptom management for patients with HF. The limited number of apps and functionalities of specific apps targeting HF behaviors suggests that the apps are in an early stage of development and that patients and providers who would be using them are at an early stage of adoption. This is also true for some older adults who have lagged behind in the adoption of smartphone technology as well [11]. One of the ongoing priorities for the adoption of mHealth apps into clinical practice will be the rigorous assessment of app quality as demonstrated in this study and effectiveness in rigorous comparative effectiveness studies. Improving the ability of apps to engage is also a targeted area for future improvement.

Figure 3. Symptom tracking features. Heart Failure Health Storylines (left image) enables tracking symptoms over time and Symple (right image) enables reporting symptoms for a single day and visualization of individual graphs by symptom.



Strengths and Limitations

Strengths of this review include applying a rigorous multistep methodology to the evaluation of the apps and using the MARS rating scale. The star rating system can be misleading given the low numbers of ratings that some of these apps have. Systematic consolidation and rigorous evaluation beyond the star rating system and user comments are needed for patients to be able to evaluate which apps may be best for their symptom monitoring and self-care. The use of the MARS was a strength because it was rigorously developed [26] and has been used to evaluate apps related to mindfulness [34] and weight management [35]. One of the limitations of this review is that apps that were not publically available were not included, such as those that required a prescription or enrollment in a specific health care network or insurance plan.

Future Research

According to a report by the IMS Institute for Healthcare Informatics, one of the most important areas for future research will be the generation of evidence of value from the use of apps that will demonstrate the magnitude of behavior change and improved health outcomes [27]. Evaluation of existing apps should use rigorously tested tools, such as the MARS or IMS functionality score. In addition, future studies should test the effectiveness of apps with higher functionality and usability scores. Further mapping of HF-specific apps to evidence-based clinical guidelines is needed. Focusing on improving apps that are already commercially available is a viable option.

In addition, there is also the need for enhanced interoperability between electronic health records and apps so that real-time data can inform clinician decision making and clinical management. Enhanced data integration should take place within the context of robust organizational governance frameworks that take into consideration the evaluation of clinical outcomes [36].

Conclusions

In general, mHealth apps offer a potentially cost-effective solution with 24/7 access to symptom monitoring at the point of need, promotion of patient engagement in their care, and can foster interactive care and communication with providers. Increasing the options for mHealth apps to support successful care management is critical. Patient collaboration with health care providers and decision making is a core component of patient engagement [37,38], improving quality of life and decreasing hospital use [39]. Our review highlights the need for further refinement and mapping to guidelines and room for overall quality improvement in HF symptom monitoring and self-care related apps. To ensure engagement, ease of use, and aesthetics, patients also need to be involved in the development of the mHealth apps.

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Conflicts of Interest

None declared.

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Abbreviations

CA-ICC: consistency-of-agreement intraclass correlation
HF: heart failure
HFSA: Heart Failure Society of America
ICC: interclass correlation coefficient
MARS: Mobile Application Rating Scale
mHealth: mobile health

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Original Paper

Characterization of Apps and Other e-Tools for Medication Use: Insights Into Possible Benefits and Risks

Linda Wilhelmina Maria van Kerkhof[1], PhD; Catharina Walthera Egbertha van der Laar[1], M Sc; Charlie de Jong[1], MSc; Marjolein Weda[1], PharmD, PhD; Ingrid Hegger[1], PharmD

National Institute for Public Health and the Environment (RIVM), Centre for Health Protection, Bilthoven, Netherlands

Corresponding Author:
Linda Wilhelmina Maria van Kerkhof, PhD
National Institute for Public Health and the Environment (RIVM)
Centre for Health Protection
PO Box 1
Bilthoven, 3720 BA
Netherlands
Phone: 31 302748688
Fax: 31 302742971
Email: linda.van.kerkhof@rivm.nl

Abstract

Background: In the past years, an enormous increase in the number of available health-related applications (apps) has occurred, from approximately 5800 in 2011 to over 23,000 in 2013, in the iTunes store. However, little is still known regarding the use, possible effectiveness, and risks of these applications. In this study, we focused on apps and other e-tools related to medicine use. A large subset of the general population uses medicines and might benefit from tools that aid in the use of medicine.

Objective: The aim of the present study was to gain more insight into the characteristics, possible risks, and possible benefits of health apps and e-tools related to medication use.

Methods: We first made an inventory of apps and other e-tools for medication use (n=116). Tools were coded by two independent researchers, based on the information available in the app stores and websites. Subsequently, for one type of often downloaded apps (aimed at people with diabetes), we investigated users' experiences using an online questionnaire.

Results: Results of the inventory show that many apps for medication use are available and that they mainly offer simple functionalities. In line with this, the most experienced benefit by users of apps for regulating blood glucose levels in the online questionnaire was "information quick and conveniently available". Other often experienced benefits were improving health and self-reliance. Results of the inventory show that a minority of the apps for medication use has potentially high risks and for many of the apps it is unclear whether and how personal data are stored. In contrast, online questionnaire among users of apps for blood glucose regulation indicates that they hardly ever experience problems or doubts considering reliability and/or privacy. Although, respondents do mention to experience disadvantages of use due to incomplete apps and apps with poor ease of use. Respondents not using app(s) indicate that they might use them in the future if reliability of the apps and instructions on how to use them are more clear.

Conclusions: This study shows that for apps and e-tools related to medicine use a small subset of tools might involve relatively high risks. For the large group of nonmedical devices apps, risks are lower, but risks lie in the enormous availability and low levels of regulation. In addition, both users and nonusers indicated that overall quality of apps (ease of use, completeness, good functionalities) is an issue. Considering that important benefits (eg, improving health and self-reliance) are experienced by many of the respondents using apps for regulating blood glucose levels, improving reliability and quality of apps is likely to have many profits. In addition, creating better awareness regarding the existence and how to use apps will likely improve proper use by more people, enhancing the profits of these tools.

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KEYWORDS

mobile apps; drugs; eHealth; mHealth; medication use

Introduction

In the past years, there has been an enormous growth in the availability of health-related applications for mobile devices, so-called "health apps" and Web-based tools, here called "health apps and e-tools". Apps are mainly used on mobile devices and are available in app stores (such as the iTunes store or Google Play), whereas Web-based e-tools are mainly designed for non-mobile devices (such as Internet applications for PC). The health apps and e-tools are designed for patients and for use by health care professionals to aid them in their daily practice.

The number of available health apps has increased dramatically from roughly 5800 in January 2011 [1], to 13,000 in August 2012, to over 23,000 health care apps in June 2013, in the United States iTunes store alone, of which 16,275 apps were for consumers [2]. Apart from the enormous increase in the availability of apps, use of health apps and e-tools is encouraged in the process to increase patient empowerment and patient participation in health care [3,4-6].

The massive increase in health apps has drawn attention of regulatory authorities, because of possible risks associated with them. Regulatory authorities have in particular concerns about apps that turn a mobile device into a medical device and, as such, need to be regulated [7,8]. Recently, the US Food and Drug Administration (FDA) has published guidelines on their control of health care apps [8]. This is followed by increased attention for health care apps by other regulatory authorities, such as the Dutch Healthcare Inspectorate [9]. In addition, numerous media have paid attention to the growing number of health e-tools and possible risks [10,11-13].

The FDA has announced to focus its regulatory actions on "higher risk mobile apps" [8,14] which mainly consist of apps that require an attachment to the phone, to enable measurement, diagnosis or treatment of a medical problem. Examples of these are apps and devices that enable a mobile phone to monitor heart function or produce tones for audiometry [14]. However, especially the availability and use of "lower risk mobile medical apps" as well as apps that are "nonmedical devices", which are not designated to convert a mobile phone into a medical device, are booming. Several previous studies have indicated that the overall quality of medical apps is poor, for example regarding accuracy, clinical usability, scientific evidence for effectiveness, adherence to guidelines, expert involvement during development and reliability [6,15-19].

In the present study, we focus on health apps and e-tools related to medication use for patients and/or health care professionals. We defined medication use as any use of licensed, prescribed or nonprescribed medicinal products by a patient, an informal caregiver or health care professional to treat a disorder or relieve symptoms of the patient. A large subset of the general population uses prescribed medicine (68% in the United States [20]; 37% in the Netherlands [21]); hence, they are the target market of a substantial subset of these tools. Importantly, they also represent a possible group of users in which risks associated with the tools might occur more easily. For example, monitoring your body weight (general health app) or monitoring your glucose levels for insulin administration (health app related to medication use) are likely associated with different risks.

The aim of the present study was to gain more insight into the characteristics, possible risks, and possible benefits of health apps and e-tools related to medication use. For this purpose, first an inventory of apps and e-tools for medication use was made. After assessment of characteristics and potential risks and benefits, one target group of often downloaded apps was selected (persons with diabetes). Using an online questionnaire, the use of apps for regulating blood glucose levels, characteristics, and experienced benefits and risks by persons with diabetes were investigated.

Methods

Search Strategy Inventory of Apps

The search strategy focused on apps and e-tools available in the Netherlands, and therefore, we used Dutch search terms. However, we included apps and e-tools available in Dutch or English, since we expected that English apps will be used by a substantial amount of Dutch users as well. To identify apps related to medication use, we performed searches in the Google Play store and Apple iTunes store. In the app stores, the following search terms were used: "medicine", "drugs", "diabetes", "asthma", "breast cancer", "prostate cancer", "cardiovascular diseases", "ADHD" and a combination of the terms "medicine" and "diabetes" (the Dutch terms can be found in Multimedia Appendix 1 supplementary data A). The terms for diseases were chosen, since these diseases are known to involve medication use, have self-management aspects, and resemble a broad spectrum of diseases resulting in a wide range of functionalities of the apps. For all terms, we included the first 20 hits. For the general terms "medicine" and "drugs", the first 50 hits were included.

In addition, to identify other e-tools, we searched several Dutch websites (n=11) using Google (for details, please refer to Multimedia Appendix 1 supplementary data A). We selected websites that publish news on eHealth technologies, are publically available, and represent different modalities of care. We searched all websites using the following search string: eHealth OR medicine OR "online tool" OR "Web-based medicine" OR "ICT and health care" OR telemedicine OR tele-monitoring OR app. In addition, depending on the website, we used only parts of this search string to avoid large amounts of irrelevant hits (eg, the term "eHealth" in a website focused on eHealth will render numerous irrelevant results, while the same term in a website for pharmacists is very useful). We performed the searches between June and October 2013.

Selection of Relevant Apps and Other e-Tools

The app and e-tool searches yielded a large number of results (app stores total: 314 apps; 217 Google Play Store and 97 from the iTunes store; e-tools: 269 messages from 11 websites). In order to filter out the relevant apps and e-tools, two independent researchers made a selection using the following criteria: (1) being an app or e-tool (defined as a tool used on an electronic device that requires some form of input, hence, this excludes

regular Internet sites); (2) clearly relating to use of medication in humans; (3) excluding apps related to alternative medicines;

(4) being available in Dutch or English, based on available app print screen or description.

Coding of Apps and Other e-Tools

We coded the selected apps and e-tools in ATLAS.ti (version 7.1.3), based on a coding scheme consisting of 16 questions about the characteristics and possible risks and benefits of each app or e-tool (see Multimedia Appendix 1 supplementary data B). Two separate researchers coded all e-tools; afterwards, we discussed discrepancies in coding until a consensus was reached. Codes were based on the information provided by the developers of the tools (information found in the ITunes Store, Google Play Store or on the Internet in case of Internet e-tools). No apps were downloaded and none of the tools were actually used.

The coding scheme was established using literature [18,22] and pilot codes. The codes are divided into three categories. The first category includes codes related to the main characteristics, which were: (1) intended goal(s), (2) intended user(s), (3) type of tool (eg, app, Internet, etc), and (4) number of downloads in the Google Play store. Unfortunately, no download data were available for the apps that were found in the ITunes Store and were thus not coded in terms of number of downloads. In the second category, we coded different aspects that are generally named as benefits of eHealth, such as lowering health costs, improving health care, enhancing patient self-management and self-reliance [23-25]. In the third category, we included codes related to the possible risks of the tools. This involved aspects such as possible (user) data upload, the absence of health care professionals when obtaining or using the tool, and the possibility of health-related harm after using the e-tool. In addition, all the tools were checked to see if they could be considered as medical devices under EU law. To properly classify and code them, the Medical Devices Guidance Document on Qualification and Classification of stand-alone software was used [7]. Classification of medical devices is based on the intended use of the developer/producer and we assessed the “intended use” on the basis of the information available in the app stores and on the Internet. If e-tools could be classified as type II medical devices, they were also coded for whether or not they could be accessed by non-health care professionals, ie, patients. For additional information on the coding criteria, see Multimedia Appendix 1 supplementary data B.

Online Questionnaire

We investigated use of apps by people with diabetes. This user group was chosen based on the finding that these types of apps are often downloaded (see Results section). Questionnaires were developed in collaboration with the Dutch Diabetes Association (DVN) as part of a larger survey into app use by persons with diabetes. The DVN has about 49,000 members, which represent 6 % of the people with diabetes in the Netherlands [26]. Questions were aimed at providing insight into use of apps for blood glucose levels, types of apps used, and experienced benefits and risks. Focus on apps for blood glucose levels were chosen since these apps are related to medication use and some of these apps might have higher risks (see Results-Inventory of Apps for Medication Use). Questions were based on the inventory codes. For overview of the questions see Multimedia Appendix 1 supplementary data C. Questback software (Oslo, Norway) was used. DVN members were invited to participate via the DVN newsletter and website. Participation was completely voluntary, anonymous, and no compensation in any form was provided for participation. The questionnaire was open for respondents for 6 weeks in May and June 2015. Participants could check their answers by going back in the questionnaire. No preventive measures were taken to avoid participants completing the questionnaire multiple times, since this is highly unlikely with the type of questions in the questionnaire (no incentive to do so for participants).

Results

Inventory of Apps and e-Tools for Medication Use

Main Characteristics

After carefully going through all the search results, 116 tools were selected as relevant for the research project by using the aforementioned selection criteria. The three most frequent (intended) functions of the tools were providing users with information/education (52.6%, 61/116), assisting users with their therapy adherence (37.1%, 43/116), and helping users monitor the effect and possible side effects of their medication (37.1%, 43/116). Less common (intended) functions included helping users choose a medication or dose (19.8%, 23/116), drug interaction monitoring (11.2%, 13/116), and providing users with news (7.7%, 9/116) (Figure 1 and Multimedia Appendix 1 supplementary data D Table D1). For examples of the apps and their functionalities, see Multimedia Appendix 1 supplementary data D Fig D1.

The majority of the selected tools were apps (87.1%, 101/116). Only 12.1% (14/116) consisted of Internet e-tools and 5.2% (6/116) could be classified as a measurement device.

In terms of intended users, the main target seemed to be patients with 59.5% (69/116) of the selected tools meant for this group. The second largest group of tools (23.3%, 27/116) aimed at the interaction between patients and health care professionals. Only 12.9% (15/116) of tools were solely targeting health care professionals. For complete overview of results see Figure 2 and Multimedia Appendix 1 supplementary data D Table D1.

We observed that the majority of the selected apps were downloaded sparsely; 59% (32/54) was downloaded less than 5000 times worldwide (Figure 3). The most frequently download category was 1000–5000 downloads per app (28%, 15/54). Only a few apps (4%, 2/54) were downloaded more than 500,000 times. It is important to note that the numbers of downloads do not necessarily equal or represent the actual usage.

Figure 1. Functionalities of the tools. Data is presented as percentage of total number of tools (n = 116). Tools can have multiple functionalities.

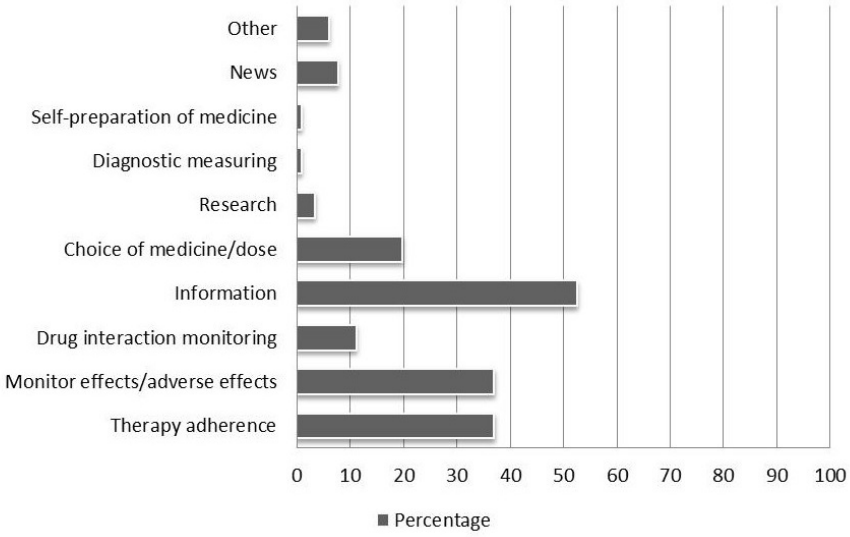


Figure 2. Intended users of the tools. Data is presented as percentage of total number of tools (n=116). Tools can have multiple intended users.

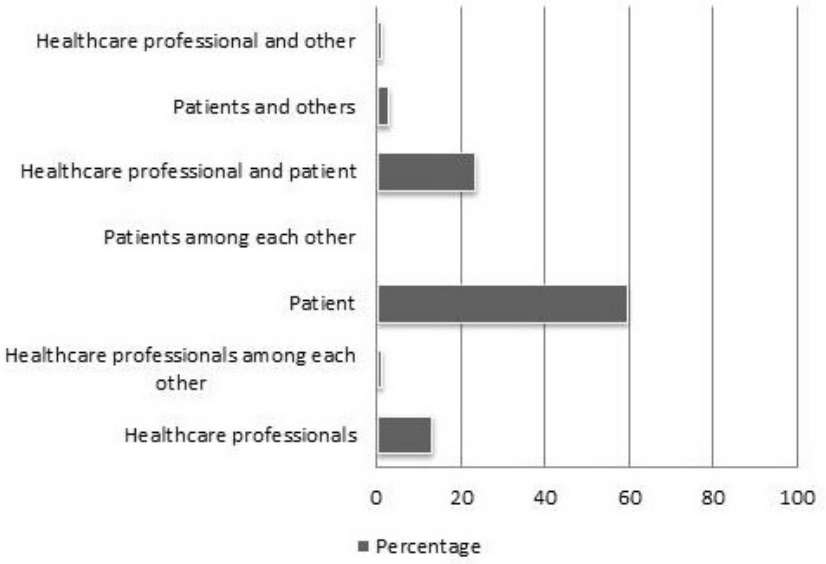
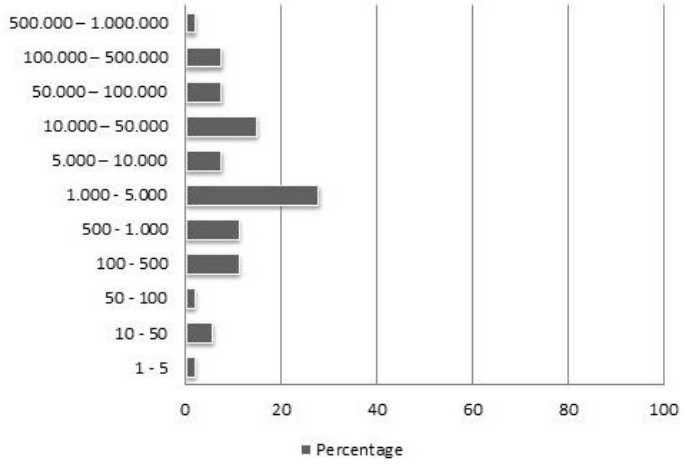


Figure 3. Frequency distribution of number of downloaded (for apps from the Google Play store). Data is presented as percentage of total number of apps (n=54).



Possible Benefits

To investigate possible benefits of eHealth tools, we selected different aspects that are generally named as benefits of eHealth, such as lowering health costs, improving health care, enhancing patient self-management, and self-reliance [23-25]. For criteria of the codes, see Multimedia Appendix 1 supplementary data B.

First, we assessed whether the tool could potentially contribute to an improvement in the user's health. This was the case in 65.5% (76/116) of the selected tools; 33.6% (39/116) of the tools did not have this potential. Second, more than half of the tools could potentially enhance a patient's self-reliance (52.6%, 61/116), while 31.9% (37/116) could not. Third, we assessed whether the selected tools had the potential to lower health care costs. More than half of them (55.2%, 64/116) had this potential while 40.5% (47/116) did not. Fourth, the tools' potential to contribute to a patient's self-management was assessed. This possible benefit was found less frequently among the selected tools than the other examined benefits and was only found in 35.3% (41/116) of the e-tools. For an overview of these results, see Table 1.

Table 1. Table . Assessment of possible benefits of apps and other e-tools for medication use; data is presented as percentage of total number of tools investigated (N=116).

Coding	Yes	No	Not assessable	Not applicable
	n (%)	n (%)	n (%)	n (%)
Potentially improves health	76 (65.5)	39 (33.6)	1 (0.9)	0 (0)
Potentially enhances self-reliance	61 (52.6)	37 (31.9)	2 (1.7)	16 (13.8)
Potentially lowers health care costs	64 (55.2)	47 (40.5)	5 (4.3)	0 (0)
Potentially contributes to self-management	41 (35.3)	56 (48.3)	3 (2.6)	16 (13.8)

Possible Risks

We coded eight possible risks of the e-tools: (1) classification as medical device, (2) data upload (privacy), (3) involvement of health care professional in obtaining and (4) use of the tool, (5) accessibility to non-health care professionals, (6) replacement of health care professional, (7) risks of erroneous use, and (8) risks of erroneous design. These possible risks are further described below. For a complete overview of criteria of these codes, see Multimedia Appendix 1 supplementary data B.

For all tools, we assessed if they could be classified as a medical device according to the EU regulations. To properly classify the tools, the Medical Devices Guidance Document on Qualification and Classification of stand-alone software was used [7]. We classified a small number of tools as a medical device (13.8%, 16/116), which were all classified as a type II medical device. The majority of tools, 86.2% (100/116), was not classified as medical devices. For none of the apps classified as a medical device, a CE mark was observed in the app store; however, since apps were not downloaded it is possible that CE mark was present in the app itself. If we classified a tool as a type II medical device, and if health care professionals were the intended user group, we also examined whether they were accessible to non-health care professionals. Only eight tools satisfied both criteria. Out of these, seven were accessible to non-health care professionals and for one app, these coding could not reliably be assessed. Thus, the majority of type II medical device tools designed for use by health care professionals were accessible to the general public. In summary, these results indicate that most apps and other e-tools related to medication use represent nonmedical devices. However, there are several type II medical devices identified with potentially high risks. In addition, the limited number of type II medical device apps designed for health care professionals are accessible to the general public.

The occurrence of data upload holds a possible risk related to privacy aspects and was therefore assessed. In most cases, the occurrence of data upload was not mentioned and thus it could not be determined whether data was uploaded or not; this was the case in 63.7% (74/116) of the selected tools (Table 2). However, in the case of 10.3% (12/116) of the tools, it was mentioned that data was only stored locally on the users device and was thus not uploaded. User data upload was specifically mentioned in 25.9% (30/116) of the tools, though it was still unclear what exactly happened with the uploaded data. These results indicate that information regarding data upload, including both the occurrence of upload and the use/storage of data, is largely missing.

For the tools designed to be used by non-health care professionals, we assessed whether a health care professional was (supposed to be) involved in *obtaining* or *using* the tool. For *obtaining* a tool, this was not the case for most tools; only 13.8% (16/116) were intended to be obtained with the help of a health care professional, while 70% (80/116) were not intended to be (Table 2). For 3.4% (4/116) of the tools, we could not determine whether or not this intention was present making assessment impossible. Roughly, the same could be seen when it came to whether or not a health care professional was intended to be involved during *use* of a tool. The majority, 68.1% (79/116), was not intended to be used with the help or involvement of a health care professional. Only 14.6% (17/116) was intended to be used in that way.

In addition, we assessed whether the tools could (accidentally) partially replace a health care professional, which is sometimes the intended aim of a tool to reduce health care costs. These were included in the benefits described above. However, (accidental) replacement of a health care professional is also a

possible risk. For only 5.2% (6/116) of the apps, we identified that they could possibly (partially) replace a health care professional, while 93.1% (108/116) could not (Table 2). These results indicate that replacement of health care professionals is not a large concern considering apps related to medication use.

Finally, we assessed if (incorrect) use of the tool or a possible error in the tool could lead to incorrect decisions with a large impact on the users' health (Table 3). In the case of (incorrect) use there was a large number of tools that (if used incorrectly) could have a negative impact on the users' health; however, in 61.2% (71/116) the chance of this actually happening was unrealistic. In only 2.6% (3/116) the chance was deemed realistic. For 34.5% (40/116) of the tools, there was no chance that (incorrect) use of the tool could have a large impact on the users' health. The chance of a possible error in the tools that could lead to decisions with a large impact on users' health was higher. This chance was deemed realistic in 6.0% (7/116) of the tools and the chance was present but unrealistic in 88.8% (103/116) of the tools. In only 2.6% (3/116) of the tools this chance was not present at all. In summary, these results indicate that most of the apps and tools related to medication have low health risks or patient safety risks; however, a small subset of the apps could be identified as having more possible health risks involved. For a complete overview of the results considering potential risks, see Table 2 and Table 3.

Table 2. Assessment of possible risks of apps and other e-tools for medication use, based on tool characteristics; data is presented as percentage of total number of tools investigated (N=116).

Coding	Yes	No	Not assessable	Not applicable
	n (%)	n (%)	n (%)	n (%)
Data upload	30 (25.9)	12 (10.3)	72 (62.1)	0 (0)
Health care professional involved in obtaining e-tool	16 (13.8)	80 (69)	4 (3.4)	16 (13.8)
Health care professional involved in using e-tool	17 (14.6)	79 (68.1)	4 (3.4)	16 (13.8)
Accessible to non-health care professionals if type II medical device	8 (6.9)	0 (0)	1 (0.9)	108 (93.1)
Replaces health care professional	6 (5.2)	108 (93.1)	2 (1.7)	0 (0)

Table 3. Assessment of possible risks of apps and other e-tools for medication use, when errors (in use or the tool) are present; data is presented as percentage of total number of tools investigated (N=116).

Coding	Yes, realistic	Yes, but not realistic	No	Not assessable
	n (%)	n (%)	n (%)	n (%)
Can erroneous use of the e-tool pose a health risk and is chance realistic ?	3 (2.9)	71 (61.2)	40 (34.5)	2 (1.7)
Can an error in the e-tool pose a health risk and is chance realistic?	7 (6.0)	103 (88.8)	3 (2.6)	2 (1.7)

Online Questionnaires Among Users

Participants

After the first DVN newsletter, 201 persons with diabetes responded. A reminder invitation was placed on the website of the organization (DVN). After this reminder, 75 additional people with diabetes responded. In total, 276 people with diabetes responded. However, 36 respondents only answered the first question of the questionnaire, "Do you use apps for regulating blood glucose levels?", but did not complete the rest of the questionnaire and were thus excluded from the analysis. This resulted in 240 respondents included in the final analysis, which is 0.5% of possible invitees (about 49,000 members of DVN).

Characteristics of Respondents

Questions regarding demographic characteristics of respondents were optional. For 208 respondents age category is known. Age distribution of these respondents is as follows: <20 years: n=13, 5%; 20-40 years: n=31, 13%; 41-65 years: n=100, 42%; 66-75 years: n=46, 19%; >75 years: n=18, 8%; no answer: n=32, 13%. Only a small number of respondents indicated to not use any type of medication for diabetes (n=5, 2%).

Use of Apps and Characteristics of Apps

Around one third of the respondents used apps for regulating their blood glucose levels, whereas almost two thirds indicated not to use apps for this purpose. A small minority of respondents indicated that they have used apps before, but stopped using them and some respondents downloaded an app for regulating blood glucose levels but never used them (Table 4). These results show that of the respondents who have ever downloaded app(s) for regulating blood glucose levels, 17.7% (20/113) never used the app and 15.0% (17/113) stopped using them after short or long term use. Indicating, that around two third of the respondents that have downloaded app(s) is using them at the moment.

Of the 147 respondents that never used apps, 23.8% (35/147) indicated that an important reason not to use apps is that they don't know how it works and 22.4% (33/147) indicated that they do not know if the apps are reliable (Multimedia Appendix 1 supplementary data E Fig E1). In addition, 51 respondents

indicated that they have "other" reasons for not using apps. The most often mentioned other reason was that they did not know apps existed (n=20). Of the respondents that indicated not to use apps anymore (n=17), 10 respondents indicated that the main reason was that the apps did not function well and took too much time.

Most respondents reported to use an app for counting carbohydrates (Figure 4). In addition, apps with a diary function and insulin dosage calculators were often used (Figure 4).

Selection of Apps

The app store is the most popular place to find (Figure 5). Thirteen respondents indicated to use other sources for finding apps. This included health care professionals (n=6) and building their own app (n=2). In addition, we asked respondents how they knew the apps that they used were reliable (68 respondents provided 80 answers). Most frequently, respondents indicated that they did not know if the apps were reliable (n=16). Fourteen respondents indicated that they check with other sources. Other responses included: assumed that the apps are reliable (n=8), apps are advised by or discussed with a health care professional (n=7), and comparison with previous measurements (n=7). Apps that perform calculations for diagnostic or therapeutic purposes are medical devices for which a CE mark is required. The majority of the respondents indicated that they did not know if a CE mark was present (75%, 21/28). Only 3 respondents indicated that a CE mark was present (11%) and 4 respondents indicated that no CE mark was present (14%) (Multimedia Appendix 1 supplementary data Fig E2).

Table 4. Use of apps for regulating blood glucose levels by persons with diabetes; data are presented as percentage of respondents (N=240).

Use of apps for regulating blood glucose levels	
Answer options	Respondents, n (%)
Yes	76 (31.7)
Not anymore	17 (7.1)
No, downloaded but never used	20 (8.3)
No	127 (52.9)

Figure 4. Types of apps used by people with diabetes. Data is presented as percentage of respondents that use apps (n = 76). Multiple answers were allowed. Two respondents using apps did not answer this question (3 %).

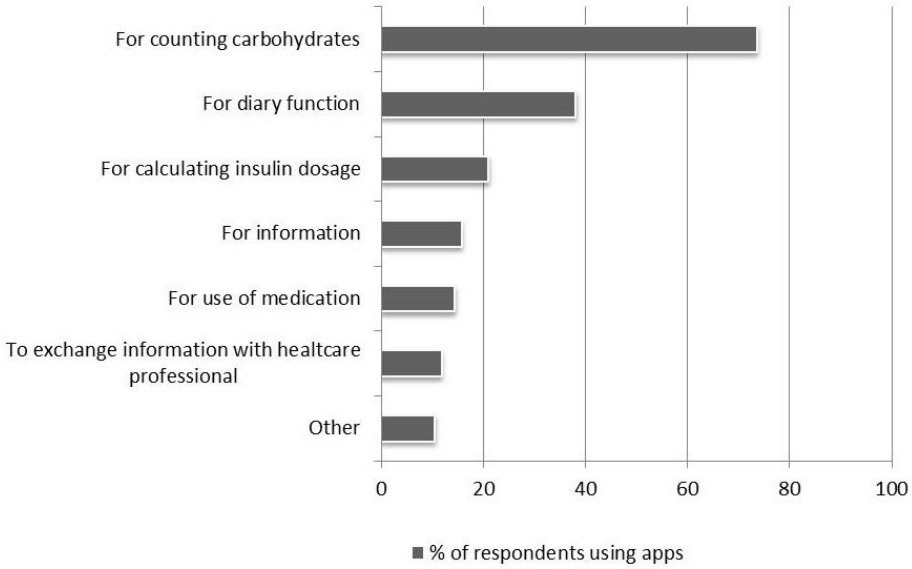
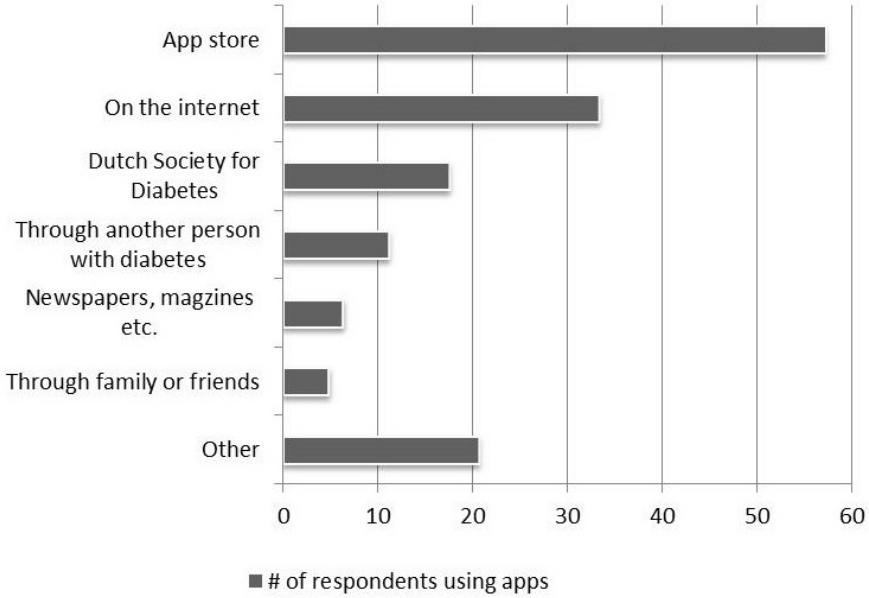


Figure 5. Popularity of different sources for obtaining aps. Data is presented as percentage of respondents using apps and that answered this question (n =63 out of 76 users). Multiple answers were allowed.



Risks and Benefits

Respondents using apps (n=76) were asked to name advantages of doing so in an open question and subsequently were asked how they experienced a set of four predefined benefits. Sixty three persons provided 82 responses to the open question. The advantages mentioned most often are: apps are convenient to use (n=26) and information quickly and simply available (n=25). Additional advantages that were mentioned are: better insight into your own health (n=16) and improves healthy lifestyle (n=8).

Respondents were asked how frequent they experience a set of 5 benefits possibly associated with the use of apps. A scale of 1-5 was used with 1 representing never and 5 representing very often. For the predefined set of 5 benefits, the benefits “information quickly available”, “improves my health”, and “improves my independency” are experienced frequently by the respondents (60 out of 76 users of apps). These benefits are experienced often or very often by 78%, 71%, and 58% of the respondents, respectively (scale 4 and 5) (Table 5). The benefit “helps with correct use of medication” is experienced not at all or rarely by two third of the respondents (65%, scale 1 and 2). Of the respondents using apps, 16 respondents (21%) did not answer this question.

Respondents who were using apps were asked to name disadvantages of using apps and subsequently, were asked how they experienced a set of 5 predefined risks.

Of the respondents using apps (n=76), 59 persons provided a total of 67 responses of which 25 respondents indicated not to experience any disadvantages. The disadvantages mentioned most often are: “apps are incomplete (information and functionalities)” (n=21) and “usage takes too much time” (n=8). Of the set of 5 predefined risks, only very few respondents indicated to experience these risks, see Table 5. Risks experienced the most frequent are problems or doubts concerning reliability of calculations and information (Table 6). Respondents were asked how frequent they experience a set of 5 risks possibly associated with the use of apps. A scale of 1-5 was used with 1 representing never and 5 representing very often. Data are expressed as percentage of respondents using apps and that answered this question (n=58). Of the respondents using apps, 18 respondents (23.7%) did not answer this question. For reliability of calculations, these risks are experienced sometimes, often or very often by 22% (13/58) of the respondents and by 19% (11/58) of respondents for reliability of information (scale 3, 4 and 5, Table 5).

Table 5. Benefits experienced by use of apps for regulation of blood glucose levels. Experiencing benefits 1.

Experiencing benefits of app use (n=76)					
	1	2	3	4	5
Information quickly available, n(%)	5 (8)	2 (3)	6 (10)	16 (27)	31 (52)
Helps with correct use of medication, n(%)	36 (60)	3 (5)	4 (7)	7 (12)	10 (17)
Helps with correctly setting insulin dosage, n(%)	21 (35)	1 (2)	10 (17)	11 (18)	17 (28)
Improves my health	6 (10)	1 (2)	10 (17)	19 (32)	24 (40)
Improves my independency	12 (20)	1 (2)	12 (20)	11 (18)	24 (40)

[1]Data are expressed as percentage of respondents using apps and that answered this question (n=60), Scale 1-5: 1=never or not applicable, 5=very often.

Table 6. Risks experienced by use of apps for regulation of blood glucose levels 1.

Experiencing risks of app use[1]n(%)					
	1	2	3	4	5
Problems or doubts concerning privacy when data is entered	46 (79)	7 (12)	4 (7)	0 (0)	1 (2)
Problems or doubts concerning reliability of calculations	38 (66)	7 (12)	11 (19)	0 (0)	2 (3)
Problems or doubts concerning reliability of information	34 (59)	9 (2)	9 (16)	0 (0)	2 (3)
Problems with availability of the app	50 (86)	4 (7)	2 (3)	1 (2)	1 (2)
Complicated use of the app	46 (79)	7 (12)	3 (5)	1 (2)	1 (2)

[1]Scale 1-5: 1=never or not applicable, 5=very often.

Respondents were also asked how they manage the risks and disadvantages of using apps, 45 respondents provided 48 answers. Sixteen respondents indicated that they use another source or look for another source. Nine respondents indicated that they do not experience disadvantages. Other responses were: accept and deal with the disadvantages (n=6), and use my own indication and/or guess (n=5).

Discussion

Principal Findings

The aim of the present study was to gain more insight into the characteristics, possible risks, and possible benefits of health apps and e-tools related to medication use. Therefore, an inventory of apps and e-tools was made and subsequently users' experiences were investigated by an online questionnaire. The present study shows that for apps and e-tools related to medication use a small subset of tools might involve relatively high risks. For the large group of nonmedical devices apps the risks are lower, but risks lie in the enormous availability and low levels of regulation. Results of the online questionnaire show that respondents using apps for regulation of blood glucose levels experience many benefits and little risks. In addition, both users and nonusers indicated that overall quality of apps (ease of use, completeness, and good functionalities) is an issue. Nonusers indicated that they might consider using apps in the future if they receive evidence regarding the reliability of apps and better instructions on how to use them.

Search Strategy for Apps and Limitations of the Study

When performing the search for apps related to medication use, we encountered several challenges. First, we used two different app stores for the present search (iTunes and Google Play store). These app stores had different search possibilities and there is no information present on how search results are provided to the consumer/researcher. Search results changed frequently, probably partially due to a change in the availability of the apps. New apps are appearing every day and apps are disappearing as well. As a consequence, the selection of apps and information related to these apps is a snapshot of one moment in time. In the subsequently performed online questionnaire, we did not focus on specific apps, but rather on one type of app users, and thus, the large dynamic content of the app stores is less an issue.

The possibilities for using search strings in the app stores are very limited. App stores are, understandably, not designed for scientific research. This limitation led to a high number of hits and enormous amounts of irrelevant apps, which made using cut-offs necessary for this study (see Methods section). Similar problems were identified in previous studies by Aungst et al as well [26-28]. Users will not perform systematic searches when looking for apps; however, they most likely encounter the same amount of irrelevant apps that they have to search through to find what they are looking for. Results of the online questionnaires among users show that the respondents mainly use the app stores for finding apps, but other sources are used as well.

Apart from the limitations of the search possibilities, other limitations of this study include the assessment of the possible

risks and benefits. To increase objectivity these assessments were performed by two independent researchers according to fixed criteria and we used an online questionnaire among users of one type of frequently downloaded apps (for persons with diabetes). However, only a small subset of users responded to the online questionnaires and therefore, the complete prevalence of benefits and risks cannot be determined. In addition, a selection bias is likely present. For example, age distribution of the respondents is somewhat younger compared to the age distribution of people with diabetes in the Netherlands [26]. Therefore, this study group cannot be seen as representable for the entire population determined. However, this study provides a good insight into possible and experienced benefits and risks and indicates where improvements need to be made.

Characteristics and Use of Apps

In our selection of tools related to medication use, the most prevalent functionalities were medication adherence, monitoring of effects/adverse reactions, and providing information. Most of the tools aid in daily use of medicines: reminders with alarms for taking medication (medication adherence) and diary functions to monitor effects/adverse reactions. Hence, these tools do not provide new functionalities compared to existing technology such as an alarm clock, a written diary, and a textbook or brochure for information. However, they make the use of these tools easier by enabling these functions on the patients' mobile phone allowing them to have these tools with them wherever they go. Results of the online questionnaires indicate that "having information quick and conveniently available" is indeed one of the most experienced benefits of using apps by persons with diabetes (78.3%).

The functionalities identified in this study are comparable to previously identified functionalities [2,27]. A study among consumer health apps available in the iTunes app store also identified a large set of apps with the "inform" functionality. In addition, "record" and "remind/alert" were functionalities identified in a substantial amount of apps [2]. The majority of the apps and e-tools investigated were aimed at patients, only a minority was aimed solely at health care professionals. However, some of the most downloaded apps were aimed at health care professionals (eg, "anesthesiologist"). Similar to a previous study by IMS [2], we observed that the majority of apps are being downloaded sparsely. Only a few apps are downloaded very frequently. One of the most downloaded apps in our selection aimed at patients was "glucose buddy", a diabetes management app. It is important to note that the data on downloads was only available for apps in the Google Play Store. In addition, it is unclear how the number of downloads represents actual usages. Results of the online questionnaire show that around two third of the respondents who have downloaded app(s) are using them at the moment. This indicates that download numbers are related to actual use of the apps to a reasonable extend.

In summary, the inventory showed that functionalities of apps for medication use are not really new compared to previously available resources. Results of the online questionnaires show that users indeed mainly use the apps because they are convenient and download numbers relate to actual use of these apps to a reasonable extend.

Possible Benefits

To identify the possible benefits of apps and e-tools, for the apps identified in the inventory, we coded different aspects that are generally named as benefits of eHealth, such as lowering health costs, improving health care, enhancing patient self-management and self-reliance [23-25]. Of these potential benefits, "improving health" and "enhancing patient self-reliance" were most prevalent among selection of apps and e-tools for medication use in the inventory. Results of the online questionnaire show that among users of apps "improving health" is experienced often or very often by more than two thirds of the respondents. Enhancing self-reliance is experienced often or very often by around half of the responding persons with diabetes. These findings indicate that the intended benefits of the apps for medication use (as identified in the inventory) are also experienced by a substantial part of the users.

Research providing evidence-based information regarding actual benefits of apps is limited [15,29]. Therefore, it is important that the use of apps and e-tools is investigated for their effectiveness at having the desired benefits (eg, improving health, lowering health costs, enhancing patient self-management etc). Interestingly, a recent study indicates that the effectiveness of a diabetes management app to "improve health" is largely dependent on patient willingness to use the app and satisfaction with the app [30], indicating the need to include these aspects in studies investigating benefits and effectiveness of e-tools. This is in line with our study, which shows that of the people willing to use the app and doing so, many feel that the app(s) improve their health.

In summary, based on the inventory and experiences of users, our study suggests that important benefits such as "improving health" and "improving self-reliance" can be gained from the use of apps.

Possible Risks and Disadvantages

We assessed possible risks of apps and e-tools related to medication use in the inventory and asked respondents using apps to their experiences. Some of these risks investigated in the present study have previously been identified as possible risks of mobile medical apps [31].

Overall, for only a small subset of the apps in the inventory, relatively high potential risks were observed (medical device and available without involvement of a health care professional). These are mainly related to apps where errors in the apps or erroneous use may lead to substantial health risks, such as apps for calculating insulin dosages for people with diabetes. The results of the online questionnaire among persons with diabetes show that, overall, respondents that use apps for regulating blood glucose levels experience little risks and disadvantages of app use.

Problems with or doubts on reliability of calculations are experienced sometimes to very often by about one fifth of the persons with diabetes using apps. This indicates that for most responding users this is not much of an issue. In addition,

respondents indicated that they have several ways to manage these risks (such as checking with multiple sources, etc). Therefore, it is not known whether problems actually have serious negative consequences. Previous studies have investigated the accuracy of medical calculation apps for medical professionals [32] and insulin calculators [18]. Bierbrier et al reported that the calculations in the medical calculation apps, including dosage calculations, were accurate and reliable with a few exceptions (mainly scorings related to liver disease) [32]. In contrast, systematic assessment of accuracy and clinical suitability of apps calculating insulin dose showed that only 1 out of 46 apps was issue-free [18]. In the present study, incompleteness of apps (regarding information and functions) and poor ease of use were the most frequent mentioned disadvantages of use by the respondents. Hence, there is clearly room for improvement regarding the quality of apps when information, functionalities, and ease of use are considered.

For the majority of apps in the inventory, it is unclear whether and how personal data is uploaded, which is relevant for patient privacy aspects. Developers should improve their provision of information regarding data upload and storage. Interestingly, results from the online questionnaires indicate that the risks with privacy are not recognized or considered relevant by most of the respondents using apps. Only a small minority of the users mentioned this as a risk of using apps, a reason not to use apps, or experienced issues with privacy sometimes.

In summary, the inventory indicated that only a few apps have potentially high risks and for many of the apps it is unclear whether and how personal data are stored. Online questionnaire among users of apps for blood glucose regulation indicate that they experience problems or doubts considering reliability and privacy very sparsely. In contrast, they do mention to experience disadvantages of use due to incomplete apps and apps with poor ease of use.

Selection of Apps and Reasons Not to Use Apps

In the past years, the availability of the apps and e-tools has increased enormously. Considering this enormous availability of apps and low levels of regulation (only a small portion of the apps in the inventory could be classified as a medical device (according to EU regulations [7,22]), patients and health care professionals might have little indications as to which e-tools are reliable. In the online questionnaire, users of apps for regulating blood glucose levels were asked how they knew if the apps that they used were reliable. Most respondents indicated that they did not know this. This problem has previously been described as well by Velsen et al [33] and by Lewis et al [31]. In this latter publication, a scheme for categorizing apps according to associated risks was described together with suggestions for assessment of these risks by, for example, peer review and/or best practice guidelines [31]. Among the respondents of the online questionnaire not using apps, “advice on which apps are reliable” was the most often mentioned requirement for them to start using apps, indicating that among potential users there is a need for better instruction or visibility of reliable apps. Recently, there have been several initiatives to make choosing reliable apps easier for patients and health care professionals by enabling peer-review. These initiatives are mainly websites where health care professionals and patients review health apps, for example: the online health apps library by the National Health Service, UK [34]; online database iMedicalApps where health care professionals review apps for health care professionals and patients [35]; online database of medical apps by a Dutch association for health care professionals [36]; appill by everhywhereIM, a database of medical apps for health care professionals and reviews by health care professionals [37]. However, it will be impossible to review and/or regulate all available e-tools due to the enormous availability and dynamic nature. As stated by Boulos et al, the best first line of defense is to educate consumers, patients and health care professionals about the risks and the proper caution that is required when using apps [15].

Interestingly, results of the online questionnaires indicate that the main reasons for not using apps are unfamiliarity with the existence of apps or with how the apps work and concerns regarding the reliability of apps. Considering the possible benefits that can be obtained from app use, improving quality of apps, awareness of apps, and how to use them, might lead to better use of eHealth benefits. It appears that there is a role for developers of apps, government agencies, health care professionals, competent authorities, patient organizations and/or other stakeholders in developing high quality apps and providing advice and instruction to patients and the general public regarding proper use of apps.

Conclusions

In summary, the present study shows that for apps and e-tools related to medication use a small subset of tools might involve relatively high risks (medical devices-class II and used by patients without involvement of health care professionals). For the large group of apps that are nonmedical devices, risks are lower, but risks lie in the enormous availability and low levels of regulation. In addition, both users and nonusers indicated that overall quality of apps (ease of use, completeness, good functionalities) is an issue. Considering that important benefits (eg, improving health and self-reliance) are experienced by many of the respondents using apps for regulating blood glucose levels, improving reliability and quality of apps is likely to have many profits. In addition, creating better awareness regarding the existence and how to use apps properly will likely improve proper use by more people, enhancing the profits of these tools.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Supplementary data.

[PDF File (Adobe PDF File), 305KB - mhealth_v4i2e34_app1.pdf]

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Abbreviations

FDA: Food and Drug Administration
DVN: Dutch Diabetes Association

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Original Paper

Creating Effective Mobile Phone Apps to Optimize Antiretroviral Therapy Adherence: Perspectives From Stimulant-Using HIV-Positive Men Who Have Sex With Men

Keith J Horvath[1], PhD; Dawit Alemu[1], MA; Thu Danh[1], MPH; Jason V Baker[2], MS, MD; Adam W Carrico[3], PhD

[1]Division of Epidemiology and Community Health, School of Public Health, University of Minnesota, Minneapolis, MN, United States
[2]Infectious Disease, School of Medicine, University of Minnesota and Hennepin County Medical Center, Minneapolis, MN, United States
[3]Community Health Systems, School of Nursing, University of California, San Francisco, San Francisco, CA, United States

Corresponding Author:
Keith J Horvath, PhD
Division of Epidemiology and Community Health
School of Public Health
University of Minnesota
WBOB, Suite 300
1300 South 2nd Street
Minneapolis, MN, 55454
United States
Phone: 1 612 626 1799
Fax: 1 612 624 0315
Email: horva018@umn.edu

Abstract

Background: The use of stimulant drugs among men who have sex with men (MSM) with human immunodeficiency virus (HIV) is associated with decreased odds of antiretroviral therapy (ART) adherence and elevated risk of forward HIV transmission. Advancing tailored and innovative mobile phone–based ART adherence app interventions for stimulant-using HIV-positive MSM requires greater understanding of their needs and preferences in this emerging area.

Objective: The purpose of this study is to (1) assess reasons that stimulant-using HIV-positive MSM download and sustain their use of mobile phone apps in general, and (2) obtain feedback on features and functions that these men prefer in a mobile phone app to optimize their ART adherence.

Methods: Focus groups were conducted with stimulant-using HIV-positive MSM (24-57 years of age; mostly non-Hispanic white; 42% once a week or more frequent stimulant drug use) in San Francisco and Minneapolis. Our aim was to explore the mobile phone app features and functions that they considered when deciding to download and sustain their use of general apps over time, as well as specific features and functions that they would like to see incorporated into an ART adherence mobile app. Focus groups were audiorecorded and transcribed verbatim. Thematic analysis was applied to transcripts using line-by-line open coding and organizing codes into meaningful themes.

Results: Men reported that they currently had a variety of health and wellness, social media and networking, gaming and entertainment, and utility apps on their mobile phones. Downloading apps to their mobile phones was influenced by the cost of the app, recommendations by a trusted source, and the time it takes to download. In addition, downloading and sustained use of apps was more likely to occur when men had control over most features of the app and apps were perceived to be useful, engaging, secure, and credible. Participants suggested that ART adherence mobile phone apps include social networking features, connections to local resources and their medical chart, and breaking HIV news and updates. Although some men expressed concerns about daily self-monitoring of HIV medication doses, many appreciated receiving a summary of their medication adherence over time and suggested that feedback about missed doses be delivered in an encouraging and humorous manner.

Conclusions: In this study, we were able to recruit a relatively high proportion (42%) of HIV-positive MSM reporting weekly or more stimulant use. These results suggest critical design elements that may need to be considered during development of ART adherence-related mobile phone apps for this, and possibly other, high-risk groups. In particular, finding the optimal balance of security, engagement, usefulness, control capabilities, and credibility will be critical to sustained used of HIV treatment apps.

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KEYWORDS

smartphone apps; technology adoption and use; men who have sex with men; stimulant drug use; HIV

Introduction

Men who have sex with men (MSM) continue to bear the heaviest burden of new human immunodeficiency virus (HIV) infections in the United States [1]. Studies show that illicit substance use remains high among MSM [2,3], with approximately half reporting non-injection substance use in the past year [4]. Among HIV-positive persons, the use of stimulants (eg, methamphetamine) is associated with decreased odds of antiretroviral therapy (ART) utilization, difficulties with ART adherence and persistence, elevated HIV viral load, and elevated risk of forward HIV transmission [5-12]. Optimizing HIV disease management reduces excess morbidity and mortality among persons with HIV [13] and lowers the probability of forward transmission to uninfected sexual partners [14]. However, it is estimated that only 27% of MSM with HIV are virally suppressed [15,16]. Therefore, advancing tailored and innovative ART adherence interventions for stimulant-using HIV-positive MSM remains a high priority [17].

The use of technology to address the HIV prevention and care needs of persons most at risk for infection and poor treatment outcomes has increased in recent years [18,19]. A recent review of technology-based interventions addressing the HIV prevention and care continuum found 18 current or in-development mobile phone-based intervention studies [20]. However, the efficacy and effectiveness of mobile phone-based intervention approaches is still largely unknown, and understanding of target populations' technology access and use is critical for advancing work in this area [20]. A qualitative study by Goldenberg et al of HIV-negative MSM's preferences for a mobile HIV prevention app showed that men favored apps that addressed multiple health issues, allowed them to connect socially with other men, and were credible, customizable to their needs, simple and easy to use, interactive, and secure [21]. Schnall et al [22] conducted focus groups of HIV-positive persons (74% male; mostly racial and ethnic minority; and 54% mobile phone users) and used self-determination theory [23] and Fogg's functional role triad [24] to assess how mobile apps may be used to meet the health care needs of people with HIV. Participants in this study suggested use of mobile phone calendars and reminders, self-monitoring of lab results, use of mobile phones for providers to reach out to patients for education and for video lectures, games, and rewards, the use of mapping systems to locate support groups, and ways to network with other people with HIV [22].

These recent studies on mobile phone app preferences among HIV-negative MSM and HIV-positive men and women provide insights into best practices for mobile phone apps for these populations. However, it is unknown whether these same preferences are held by stimulant-using HIV-positive MSM, who may have different technology-assisted prevention and treatment needs than their HIV-negative or non-stimulant-using counterparts [25]. Therefore, we conducted focus groups with stimulant-using HIV-positive MSM to address two primary research questions: (1) What features and functions of mobile phone apps does this population consider when deciding to download and sustain their use of apps over time, and (2) What features or functions do these men prefer in a mobile phone app to help them manage ART adherence?

Methods

Participants

Five focus groups, two in San Francisco and three in Minneapolis, were conducted in April-June 2014. Participants for the focus groups were recruited through local acquired immune deficiency syndrome (AIDS) service organizations, substance abuse treatment centers, and word of mouth. A total of 26 participants (16 from San Francisco and 10 from Minneapolis) participated in the study.

Inclusion criteria for the study were self-reported: (1) male 18 years of age or older, (2) having had sex with another man in the past 5 years, (3) stimulant use (methamphetamine, cocaine, crack cocaine, amphetamine and/or ecstasy) in the past 6 months, (4) diagnosis of HIV and taking ART, (5) having access to or owning a mobile phone with mobile phone features, and (6) English speaking.

Procedures

All procedures were approved by the University of Minnesota Institutional Review Board. Focus group questions were developed by the research team and guided by the Technology Adoption Model (TAM) [26]. The TAM is a conceptual model to capture how persons will come to accept and use a new technology, such as the perceived usefulness of the technology and how easy the technology is to navigate. Participants were asked to describe what apps they currently have on their mobile phone. Next, men were asked to reflect on features and functions of mobile phone apps in general that they believed contributed to their decision to download, initiate use of, and continue to use apps. Although focus group members often spontaneously mentioned many features (eg, perceived usefulness) of their general app downloading and use that were relevant to the TAM conceptual model, we probed men to reflect on factors of the TAM conceptual model that were not mentioned. Finally, men were also asked to describe features and functions that they would like to see in ART adherence apps.

Recruitment materials included a link to the study website where interested persons were welcomed and asked to complete eligibility screener items, from which sociodemographic and drug use data in Table 1 were obtained. Those who met eligibility criteria were asked to provide consent. Focus groups were conducted in confidential settings in both locations. To maintain confidentiality and promote truthful answers to socially sensitive questions, participants were encouraged to use and refer to each other by their first name only. Focus group

discussions lasted from 90-105 minutes. All focus groups were digitally recorded and later transcribed for analysis.

Data Analysis

Thematic analysis was used to analyze transcripts [27]. Qualitative codes were developed using line-by-line open coding for all transcripts [28], with the unit of analysis being a complete thought reflecting one of the codes. As such, the unit of analysis could range from several words to multiple sentences. First, 2 authors (DA and TD) coded one transcript to individually identify preliminary themes (DA and TD). The authors met to discuss their themes and refine the coding scheme. Once codes were agreed upon, the remaining transcripts were coded. Disagreements were resolved with discussion [29]. Finally, 3 authors met (KH, DA, and TD) to debrief about the study findings and organize the themes within meaningful categories (as described below).

Results

Participants were 24-57 years of age, with an average of 43 for men in San Francisco and 40 for those in Minneapolis. Most men were white (25/26, 96%) and non-Hispanic (23/26, 88%), and the average self-reported ART adherence in the past 2 months was 87%. There was a variation in frequency of stimulant drug, with 42% of men reporting stimulant drug use at least once a week or more frequently (see Table 1).

Table 2 shows the apps that men in the focus groups reported currently having on their mobile phone. Overall, men reported downloading and currently using a variety of health and wellness, social networking and dating, gaming and entertainment, and utility apps. Of relevance to stimulant-using HIV-positive MSM, focus group members reported currently having apps to assist them with maintaining their sobriety, clinical care, insurance, pharmacy, medications, and HIV.

The study team organized themes that emerged from the focus groups into three main categories: reasons men downloaded apps to their phones, general app design features that convinced men to download and sustain use of apps over time, and preferences for components and features of an ART adherence app. The organization of the themes and definitions are shown in Table 3.

Table 1. Focus group sociodemographic characteristics.

		Total, N=26	San Francisco, n=16	Minneapolis, n=10
Age (in years), mean		41	43	40
Race, col%[a]				
	White	96	94	100
	African American	4	6	0
Ethnicity, col%[a]				
	Hispanic	12	13	10
	Non-Hispanic	88	87	90
ART adherence, %	Self-reported in past 2 months[b]	87	87	86
Stimulant drug use, past 6 months, col%[a]				
	Less than once a month	23	6	50
	Once a month	23	30	10
	Every couple of weeks	12	12	10
	Once a week	22	25	20
	2-5 days a week	8	12	0
	Almost every day or every day	12	12	10

[a]Column percentage.

[b]ART adherence was assessed with the following item: “What percent of your prescribed HIV medication have you taken in the last 60 days (or about the last 2 months)? This may not be 100% for many people (eg, 0% means you have taken no medication, 50% means you have taken half your medication, 100% means you have taken every single dose of medication and at your usual scheduled time). If you’re unsure, make a best guess” with a pulldown menu of percentages from 0-100% with response options at 1% increments.

Table 2. Types of apps downloaded by participants.

App types		Examples
Health/wellness apps		
	General/other health	WebMD, Sobriety Day Counter, First Aid, Run Keeper
	Clinic/Insurance/Pharmacy	Kaiser Permanente, MyChart, Blue Cross/Blue Shield, Walgreens
	Medication	Pill Finder, Prescription Tracker
	HIV	HIV Plus
Social media/networking apps		
	Social networking	Snapchat, Facebook, Twitter, Skype, YouTube, TubeMe, WhatsApp, Viber
	Dating/sex seeking	Grindr, Scruff, Growlr
Gaming/entertainment apps		
	Movies, TV, and photos	Netflix, Flickr, Flickster
	Music	Spotify
	Gaming	Candy Crush Saga
Utility apps		
	General/Other	Google Maps, Smart Ride, Google Chrome, Dropbox, Calendar, Dual Lingo, Yelp, Photoshop
	Banking	Wells Fargo, TCF Banking

Table 3. Themes and definitions.

Theme	Definition
Reasons to download an app	
Cost	How much is acceptable for an app to cost to consider downloading an app
Recommendations from friends	Downloading an app was influenced by recommendations from friends
Time to download	The time it takes to download influenced men's decisions to download the app to their phone
App design features associated with downloading *and* sustained use	
Control	Beliefs that having control over the different features/functions of the app is important
Perceived usefulness	Beliefs that an app makes their life easier or is useful in their lives
Engaging	Statements that an app has to be visually engaging, fun, and/or keep them interested
Credible	Beliefs that the app has to be credible or come from a credible source
Security/Privacy	Statements about security and how that might influence downloading or using an app
Ease of use	Perception that the app is simple or easy to use or simple to navigate
Preferences for ART adherence app features and functionality	
Social networking	Beliefs that being able to network with other HIV positive people would be useful
Resources	Statements that using the app to connect with local resources to help them manage their HIV or other nearby community resources would be helpful
HIV news/updates	Having updated HIV information would be useful
Synching capabilities	Beliefs that synching the app to other apps on their mobile phone/computer or synching with their electronic medical record would be helpful
Reminders for health care	Having a reminder for their medical appointment and other medical needs is important
Self-monitoring	Perceptions of how medication reminders should operate and specific ideas for medication reminder system
Adherence performance feedback	Statements about how feedback about their ART adherence performance or other aspects of their life (eg, diet) should be presented
Graphing and summarizing	Participants' desire to have a feature that would graph their ART adherence performance or summarize their health over time
Health file	Men's beliefs that having a place to store their health information would be valuable

Reasons to Download an App

Participants identified three reasons that contributed to downloading an app to their phone.

Cost

Most men preferred a free app. However, some men did not mind paying a modest amount for an app so long as they heard about the product from a trusted source: "I might pay for an app if I know that it's really good and someone has recommended it but I'm certainly going to try the free version first" (41, non-Hispanic white, stimulant use once a week).

Recommendation From Friends

A recommendation from a friend was key in men's decisions to download an app: "Word of mouth, like if someone says, 'Oh this is a great app,' then I'm probably going to use that then too" (44, non-Hispanic white, stimulant use less than once a month).

Time to Download

The time it takes to download an app was another key consideration in their decision to download an app. Most men favored an app that takes little time to upload or update. As one respondent noted: "you sit there and wait, you know, forever for it to upload and, you know, somebody's standing right next to you. He's on a different app, and there's his immediate" (49, non-Hispanic white, stimulant use almost every day or every day).

Design Features and Functions Associated With App Downloading and Sustained Use

Participants identified six general design features of apps that they used to determine whether they would download an app to their phone and continue to use it over time.

Control

Overall, men were comfortable with most features of an app as long as they had control over it: "all of the features should really be under the control of the user…very customizable. This is I think what…what keeps me coming back, knowing that I can adjust" (48, non-Hispanic white, stimulant use almost every day or everyday). Some of the features men want to have control over include setting up alarm features, getting email reminders, and push notifications:

> *When you got it registered, ask more push notifications, then that just kind of makes it simple*

> *for…for everybody. I mean, you know, if you don't like push notifications, you can…check that box. If you do like push notifications, you can. And it…makes it available for those who do like it…But it is not a hassle for those who don't, at the same time. I think that would just make it easy.* [27, African-American, stimulant use less than once a month]

Perceived Usefulness

Participants believed that apps should be something that they can integrate into their daily lives, and they may delete apps that are not functional:

> *For me, um, you know, apps is usually, uh, it's, it's gonna be functional...if it seems relevant or could be helpful, you know, I'll just get, get one to, to browse. And then the thing that I do is to explore. What I do is I, uh, I don't have apps I don't use on my phone. I get rid of them.* [42, non-Hispanic white, stimulant use every couple of weeks]

Men stated that the app should be something that enhances their life and takes care of their basic needs. As one participant stated, "It definitely is practical. You know, is it working in my life? How can it enhance my life? Not just, you know, just to have on the phone" (37, non-Hispanic white, stimulant use almost every day or every day).

Engaging

Overall, men would like to see visually engaging apps that use bright colors and interactive features: "It has to be really fun and like, interactive and you know, it has bright colors and you know, that's a good thing" (27, African-American, stimulant use less than once a month). Most men agreed that an app that was not engaging would be reason for discontinuing its use: "if it looks like a spreadsheet…I'm not gonna use it. You know…or if it's just too clinical, you know, as to the color and…the design and style" (46, Hispanic white, stimulant use once a week).

Credible

Nearly all of the participants agreed that the app should come from a trusted source. Some mentioned universities as examples of possible trusted sources of the future app to be developed. They also mentioned that the source should be displayed for the users to easily see:

> *I think um, knowing the um, the source of the app is pretty important, like, credible, reliable you know, sources right up front so that…you know, it's like university would be, obviously, credible, you know. They wouldn't be any doubt.* [42, non-Hispanic white, stimulant use once a month]

Security/Privacy

There was some variation in men's concern with regard to privacy, with some men expressing little concern about security while using apps, while others were reluctant to disclose too much personal information over concerns about security:

> *So I found out about this HIV Plus and installed it, and it really wanted to know everything about me possible. And I thought, my god, I'm not entering all that information on an app on my telephone. You know, I'm just not gonna do it. And so I never used it. Ever* [41, non-Hispanic white, stimulant use less than once a month]

Others were comfortable sharing their personal information as long as they are informed about the need for the information. As one participated stated, "As long as it's clear as to what …what it wants to access and why…I'm usually okay" (46, non-Hispanic white, stimulant use less than once a month).

Men preferred a tight security system on the app and suggested several layers of security to be put in place, especially using more than one password, to safeguard their account. However, participants also mentioned that they do not want to be asked to change their online security information frequently, as is required by some apps:

> *And so I would want to make sure that there is going to be adequate protection…so I would consider a couple layers, I mean, definitely, more than one password, um, but I don't want constantly changing security questions every three months and on and on and on that some of the sites do.* [54, non-Hispanic white, stimulant use every couple of weeks]

Ease of Use

Overall, men wanted an app that was simple to use: "it needs to be easy…the more complicated you make it, the less easy it is" (41, non-Hispanic white, stimulant use less than once a month). Consistent with this, participants preferred infrequent changes in an app since learning new features is time consuming:

> *What I really hate is when the app changes the configuration and you go to it and it looks like a completely different thing and uh, because of an update. And you have to go and you to relearn this whole process to get to what you want to get at. And that's annoying. And…and especially how often they have updates and changes. And it's like, "Okay. That wasn't necessary. And now, it's just a bunch of work." And…and the more it changes they have and the more work it is, the less I'm opt to use it.* [42, Non-Hispanic white, stimulant use once a month]

Preferences for Antiretroviral Therapy Adherence App Features and Functionality

Nine themes related to men's preferences for features and functionality of an ART adherence app emerged from the focus groups, which are described below.

Social Networking

Nearly all men expressed their desire to connect with other people having the same HIV status. Some preferred a dating site where they can meet other men for sex in a confidential manner:

> *To being able to…reach out to…people who have HIV in your community. Um, I know that a lot of apps like Grindr and more sexual hookup type of sites that are probably end up happening on that as well. It*

> *doesn't have the app advertised that way. They advertise those you know, meet other private people who are in your neighborhood and…still, maintaining that confidentiality, you know.* [27, African-American, stimulant use less than once a month]

Other men were looking for a kind of forum (discussion board) where they can post and respond to HIV-related experiences as a way to learn from each other's experience:

> *I think, like, a question answer, like, when you've got questions about what's going on, or with your meds, or your treatment, you know, like, not necessarily a doctor, but kind of like a WebMD, like, how you can post questions or look through other people's experiences that they may have talked about. Yeah, like, sometimes to go, "Hey is there anybody out there going through this with…Or be like a, look, like, almost a frequently asked questions type of thing where you can go look. Like, type, search symptoms with or side effects with a certain drug and see what people have said. Cause I've read in magazines and stuff, oh these are the side effects that you could have, but I like to talk to other people about it.* [44, non-Hispanic white, stimulant use less than once a month]

Resources

Participants mentioned the need to connect to local resources via an app (eg, mental and dental health resources), as well as health education resources that will help them manage their HIV: "I would love local content and that's I what I think I get from my [local HIV] group, local content…that would keep me going back and then it comes back to the relevancy issue" (41, non-Hispanic white, stimulant use once a week).

HIV News/Updates

Some men would like to get information on the latest breakthroughs in HIV medications and related stories that would be relevant or in some way apply to their own life:

> *I have some news apps and I'll give you breaking news about different things because I'm a news junkie, but I would appreciate hearing about breakthroughs in HIV or new studies or things like that that are relevant to me that I might want to consider.* [54, non-Hispanic white, stimulant use every couple of weeks]

Participants also mentioned their desire to find something new and engaging every time they go to their mobile app:

> *That's one I have to say about the [local HIV group] in Facebook is that [it has] things to really keep me engaged and every time I go back there I'm like I'm going to find an interesting conversation. I'm going to find an interesting news story. There's a new event. There's this constantly something. I know it's a lot of work but that to me has kept me engaged in its community that I need and what information about.* [49, non-Hispanic white, stimulant use every couple of weeks]

Synching Capabilities

Most participants wanted to see the app synchronized to their other medical records so that it would be easier to keep track of their medical information and have their history readily available during their appointments. They also mentioned the need for synching an adherence app with other computing devices. As noted by one participant, "to have it that you can interface it with your computer. Actually you have the same information on your computer…that will sync up with what you got when you put your password or whatever in" (44, non-Hispanic white, stimulant use less than once a month).

Reminders for Health Care

One aspect mentioned by men was the need to get a doctor's appointment reminder: "being able to integrate it with your provider…your provider's information. Now there are simple things, you know, to integrate with your calendar so that it reminds when your next doctor's appointment is. Yeah, simple stuff like that" (46, Hispanic white, stimulant use once a week). Men also indicated the importance of getting a reminder for their medication refill: "Maybe even linking it to your pharmacy so that you could do maybe a refill from that particular app I don't know if that's possible, 'cause I have an app for a refill service and it sends me notifications as when it's ready" (37, non-Hispanic white, stimulant use almost every day or every day).

Finally, men wanted reminders for managing other aspects of their HIV health care: "Maybe like along the lines of putting in reminders…to send in your program HH [Health and Human Services] paperwork...or information like if there's something coming up with renewing Ryan White something or something to call your Senator or whatever, maybe" (24, non-Hispanic white, stimulant use once a month).

Medication Dose Reminders

Men who frequently struggled to remember to take their medication expressed interest in dose reminders through a mobile app:

> *I've never been med adherent for like the last three years and um, and it's mainly because I always forget. I'm a very forgetful person and um, which is kind of the scary thing but I think like this app thing is kind of cool and I think what would what would be helpful for me if I were to download that app… is like having that notification at the same every day.* [28, non-Hispanic white, stimulant use once a week]

Some men particularly mentioned a need to get a reminder at times they were most likely to forget:

> *I think definitely the reminders is probably the biggest piece. Um, and actually tracking for me. So some sort of reminder about taking the medicine and then if you're you know, maybe over the weekend if you're a frequent hangout at your friend's house over the weekend and you're not home, are you prepared? Did you take your medicine with you when you packed all your essentials? Um, so it would be along those*

> *lines.* [37, non-Hispanic white, stimulant use almost every day or everyday]

However, the need for daily dose reminders was not shared by all men, and some men noted that reminders should include more features than they would normally have in their phones: "at the same time, I think that, like, with the specific idea that you wouldn't want it to be too simple, cause I've already got, like, on my calendar a reminder to take my meds" (24, non-Hispanic white, stimulant use once a month).

Graphing and Summarizing

Although some participants did not want to receive reminders for medication doses, they did express interest in being shown a summary of their medication taking over time: "the idea of having to do something every day…does not appeal to me at all, but the benefit of seeing what patterns are in my life over a period of time, I might be willing to commit to doing something and to try that" (54, non-Hispanic white, stimulant use every couple of weeks).

Men noted that such a feature would help them keep an accurate record of the number of days they have missed their medication and bring that up to their doctor's appointment: "The second thing is it would be nice if, at the end of the month, it would tell me how many doses I missed...Because some of the, you know, things that I do, like checkups with my doctor, they want to know that" (35, non-Hispanic white, stimulant use once a month).

Other participants wanted this feature so that they could use the information as motivation to adhere more consistently to their medication:

> *I wanna see what my numbers are for that month. So…the next time I go to the doctor, let's say I missed two weeks for whatever reason, which I have...I can see that my numbers went down just so that I can put in my numbers, you know, into the calendar when do I get my checkups...so that I have a visual to say, you know, these people aren't full of shit, that it really does matter, or something like that.* [46, non-Hispanic white, stimulant use once a month]

The quote above reflects this participant's belief that logging periods of ART non-adherence could motivate him to be more adherent by providing clear evidence that missed doses directly affects his health during subsequent visits to his health care provider.

Adherence Performance Feedback

Participants wanted to receive a message that will positively reinforce their medication adherence: "every time I look down at the app, if there was something that spoke to a statistic, a study statistic about the power of adherence…because to me, in addition to the check-in, if I saw that and I hadn't taken them yet, that might motivate me to say 'You know what?'" (49, non-Hispanic white, stimulant use every couple of weeks).

Men noted that feedback should avoid being presented in a parental or shaming manner, while some men thought that using humor to provide feedback about missed doses would be effective*:* "if you're gonna do motivational, positive messages...you should say 'Hey, idiot, you forgot your medicine.' You know, which makes it hilarious for me" (46, non-Hispanic white, stimulant use almost every day or every day).

Health File

Overall, men expressed their need to have a file where they can store all their health-related information. As one participant noted, "So it is nice to have one location where all your medication and stuff is, if you need it in an emergency situation" (54, non-Hispanic white, stimulant use every couple of weeks).

Discussion

Principal Results

The successful dissemination and uptake of mobile phone app interventions addressing the HIV prevention and treatment continuum of care requires that persons are willing to download and sustain use of the app, as well as providing content and features that are culturally relevant for the target population. In this study, we explored the features and functions of mobile phone apps that stimulant-using HIV-positive MSM considered when deciding to download and sustain their use of apps in general over time, as well as specific features and functions that they would like to see incorporated into an app to help them manage ART adherence more effectively.

Men who participated in these focus groups appear to already be using a variety of mobile phone apps to help them manage HIV and substance use. When asked about apps they currently had on their mobile phones, participants stated that they had apps to help them navigate their health care (eg, clinic, insurance, and pharmacy apps), medications, and HIV. In addition, at least 1 participant noted that he used an app to track the number of days of sobriety. These results suggest that apps designed for stimulant-using HIV-positive MSM will need to fill a unique niche between currently available apps for HIV and apps addressing substance use. To our knowledge, there are no current apps that specifically address the intersection of HIV and stimulant use. Given that stimulant-using HIV-positive men are at high risk for ART adherence problems [5,6,11], developing an app that incorporates the lessons learned in this study is warranted.

There were three features specific to men's decisions to download an app to their phone. Men believed apps should be either free or very low cost. However, men scrutinized apps with some cost associated more so, by reading reviews or asking for suggestions for their friends. In contrast, men stated that they were inclined to download a free app to their phone that they knew little about since there was no cost involved and they could easily remove it from their phone later. Recommendations from friends appear to be an important motivator to men in this study, with respect to downloading an app. HIV app developers should consider ways that stimulant-using HIV-positive MSM can easily recommend an app to friends as an avenue to disseminate the app broadly, such as including a way to send an email or text to friends with the app information and downloading instructions.

Perhaps the greatest challenge to ensuring the dissemination and longevity of HIV prevention and treatment apps is to understand the features and functions that will motivate men to sustain their use of these apps over time. Stimulant-using HIV-positive MSM in this study noted several features and functions that were associated with downloading *and* sustained app use, including having control over most features of the app, how useful and engaging it was, its security features, and the credibility of the app. A prior study of HIV-negative men's preferences for an HIV prevention app found similar sentiments [21]. These are common components of technology adoption models [26] and many of these dimensions —especially creating interventions that are engaging and useful—are common "best practices" across most technology platforms [30]. We found it noteworthy that some men in this study appeared to express little concern about security of apps on their mobile phone. This is, in part, likely a self-selection bias that men who are willing to participate in focus groups are more open about sensitive personal information, such as their HIV status. However, this finding also suggests that app developers should weigh the costs and benefits of each security feature of the app to ensure that these features are not overly burdensome, since low burden is an influential factor for adoption and use of technologies [31]. Finding the optimal balance of security, engagement, usefulness, control capabilities, and credibility will be critical to sustained use of HIV treatment apps.

There were a number of different features and functionality preferences stimulant-using HIV-positive MSM would like to see incorporated in an ART adherence mobile phone app, many of which reflected the preferences of HIV-positive men and women in a prior study by Schnall et al [22]. Men in the current study expressed a desire to connect with outside local and social network resources through the app, including socializing with other HIV-positive men, connecting to local mental health and other resources, viewing breaking news about HIV, and connecting to their medical chart. Although connecting to external resources and health records undoubtedly would be helpful for persons with HIV, there are significant barriers to achieving some of these recommendations. For example, integrating an ART adherence app with commercial apps (eg, dating and sex-seeking apps such as Grindr, Scruff, and Growlr) or electronic health records requires agreement from, and coordination with, the leadership and developers of those outside organizations (such as developers of health care apps, including MyChart or Kaiser Permanente). A platform for building relationships between researchers wishing to test HIV prevention and treatment apps and existing health and for-profit companies is needed to advance cooperation between these key stakeholders.

Other app features and functionality preferences that men noted were specific to ART adherence self-monitoring, including whether receiving medication dose reminders was acceptable, what information about their adherence performance would be helpful and how to frame feedback in response to missed doses. Overall, although there was some concern about monitoring each dose of medication, men were in favor of seeing a summary of their ART adherence performance over time. They stated that receiving such feedback may motivate them to be more adherent by directly seeing a summary of their performance over time. In addition, they could use the summary during appointments with health care providers to communicate more accurate estimates of their ART adherence. ART adherence app researchers may want to include explicit benefits of daily dose monitoring to participants using the app to increase "buy-in" to self-monitor medication doses. Finally, men expressed the desire for feedback about missed doses to be framed in a positive, non-authoritative, and possibly humorous way. These same qualities about the language and tone of successful apps were reflected by HIV-negative MSM in a recent study [21].

Limitations

There are some important limitations to this study. First, the results from these focus groups are not intended to be generalizable to all stimulant-using HIV-positive MSM, persons with HIV, or MSM in general in the United States. Most men in this study were non-Hispanic white, which does not reflect the racial and ethnic distribution of HIV in the United States [1]. Thus, future research should assess mobile phone app preferences among a more diverse sample of MSM to determine whether similar attitudes are expressed. In addition, we recruited men residing in or near only two metropolitan areas, San Francisco and Minneapolis. Therefore, these results may not reflect men living in other areas of the United States or more rural regions. These results are meant to be first steps in more fully understanding the needs of stimulant-using HIV-positive MSM with respect to mobile phone apps to address ART adherence.

Conclusions

Despite the limitations of this study, we were able to recruit a relatively high proportion (42%) of participants reporting weekly or more stimulant use. Advancing novel ART adherence interventions for these men are particularly necessary given that weekly or more frequent stimulant use has been found to be associated with intermittent ART utilization and elevated viral load [32]. The results from this study suggest critical design elements that may need to be considered during development of ART adherence-related mobile phone apps for this, and possibly other, high-risk groups.

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Conflicts of Interest

None declared.

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Abbreviations

AIDS: acquired immune deficiency syndrome
ART: antiretroviral therapy
HIV: human immunodeficiency syndrome
MSM: men who have sex with men
TAM: Technology Adoption Model

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Original Paper

Assessing the Use of Mobile Health Technology by Patients: An Observational Study in Primary Care Clinics

Veronica Ramirez[1], MD; Emily Johnson[2], MPH; Cesar Gonzalez[2], BS; Vanessa Ramirez[2], BS; Barbara Rubino[1], MD; Gina Rossetti[1,2], MD

[1]Department of Internal Medicine, Los Angeles County + University of Southern California Medical Center, Los Angeles, CA, United States
[2]Keck School of Medicine, University of Southern California, Los Angeles, CA, United States

Corresponding Author:
Veronica Ramirez, MD
Department of Internal Medicine
Los Angeles County + University of Southern California Medical Center
2020 Zonal Avenue, IRD 620
Los Angeles, CA, 90033
United States
Phone: 1 323 226 7556
Fax: 1 323 226 2657
Email: ramirezv@usc.edu

Abstract

Background: There is significant potential for mobile health technology to improve health outcomes for patients with chronic diseases. However, there is a need for further development of mobile health technology that would help to improve the health of lower-income communities.

Objective: The study objective was to assess mobile phone and app usage among a culturally diverse patient population, and to determine whether patients would be interested in using mobile health technology to help manage their chronic diseases.

Methods: An observational study was conducted with patients of the Internal Medicine resident primary care clinics of Los Angeles County and University of Southern California (LAC+USC) Medical Center. Self-reported information regarding demographics, current mobile phone usage, current mobile health app and social media usage, barriers to using mobile phones or mobile health apps, and interest in using a mobile health app was collected.

Results: Ninety-one percent of patients owned a mobile phone, with 76% (169/223) of these reporting having a mobile phone with Internet capability. Fifty-seven percent of subjects used mobile apps on their mobile phones, and 32% (41/130) of these used mobile apps related to their health. Eighty-six percent (207/241) of respondents voiced interest in using a mobile app to improve their health, and 40% (88/221) stated they would use such an app daily. Patients stated they would find the mobile health app most useful for nutrition, exercise, and obtaining general information on medical conditions.

Conclusions: Despite the fact that the majority of our primary care patients were of lower socioeconomic status, they utilized mobile phones with Internet and mobile app capabilities to a great extent. There was substantial interest among our patients in using mobile health technology to both manage chronic disease and improve overall health. Given that cultural, educational, and socioeconomic disparities strongly correlate with higher rates of chronic diseases such as obesity, diabetes and hypertension, access to culturally relevant mobile health tools may empower patients in these populations to improve health outcomes.

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KEYWORDS

Mobile health applications; mobile health technology; telemedicine

Introduction

Mobile phones have developed into more than just a convenient way to place a phone call. These devices have become tools necessary to complete such tasks as managing a schedule, checking urgent work emails, and even keeping track of physical activity. In 2012, 85% of American adults owned some type of mobile phone [1]. In 2014, 64% of American adults owned a smartphone [2]. For the health professional, a mobile phone has become an integral part of the delivery of health care. Mobile

health technology, or simply, *mHealth*, has experienced incredible growth in the last ten years with the widespread adoption of smartphones. The principle components of *mHealth*, such as text messages (SMS) and mobile health apps, give health providers quick access to medical information in order to help care for their patients. In return, patients have utilized *mHealth* to take more active roles in managing their own health. In 2012, 31% of mobile phone owners reported using their phone to search for health or medical information on the Internet, and 19% of mobile phone owners reported using mobile health apps to track and manage their health [1]. In a descriptive analysis of "health and wellness" apps available on the Apple iTunes Store in 2014, the most popular mobile health apps focused on self-monitoring of exercise, diet, and weight management [3], indicating that developers see a market in individuals interested in taking a more proactive role in managing their health.

Though mobile health apps continue to be researched and developed, the role of *mHealth* in chronic disease management in patients that belong to culturally, linguistically, and economically diverse communities remains an area of ongoing work. Historically, a "digital divide" has existed in which individuals belonging to such communities lack access to digital information (especially Internet access) because of their particular demographics [4,5]. However, several studies have shown promise that the digital divide may be gradually closing as the Internet and mobile technology become more readily accessible to underserved populations. In the 2013 Hispanic Trends Project of the Pew Research Center, it was observed that Latinos owned mobile phones and went on the Internet from mobile devices at similar, and even sometimes higher, rates than did other groups of Americans, and it was very likely these trends would continue to increase [6]. Therefore, there needs to be further research into how such populations, who historically suffer from significant health disparities, may benefit from the development of culturally and linguistically tailored mobile health technology.

The purpose of this study was to investigate mobile phone usage among patients at the Los Angeles County and University of Southern California (LAC+USC) resident primary care clinics, which serve a diverse patient population. We aimed to assess how patients utilize various types of mobile technology, and to what extent our patients use mHealth. We also wanted to assess need for and interest in using mobile health technology, such as mobile phone apps and social media, to help manage health (for example, obtaining information regarding nutrition, physical activity, and chronic disease management). As a secondary aim, we were interested to determine whether demographic factors predicted engagement with social media and mobile phone apps, given that there is expanding growth in reaching these patients via these mobile health platforms.

Methods

Survey Development

The study was approved by the Internal Review Board of the University of Southern California. An electronic survey of 25 questions was designed by a team of general internists familiar with the target patient population. Based on a literature search of research surveys regarding mobile health [1-2,5], questions were selected and modified for our patient population. The survey assessed several categories (the full survey is available in Textbox 1).

Textbox 1. The 25-question electronic survey.

1. What is your age?
2. What is your sex?
3. What is your ethnicity?
4. What is your primary language?
5. What other languages do you speak?
6. What is your annual household income?
7. What is your highest level of education?
8. Do you own a cellular phone?
9. If yes to #8, what kind of cellphone are you using (with or without internet capability)?
10. If your cellphone has internet capability, do you use the internet?
11. If you use the internet on your cellphone for your health needs, what website do you use?
12. Do you know what the definition of a cellphone application (app) is? If so, please explain.
13. Do you use your cellphone to access applications?
14. If yes to #13, do you use applications related to your health?
15. Please list the cellphone applications related to your health that you use on a regular basis.
16. If you do not have a cellular phone that accesses the Internet/applications, do you know someone who does?
17. If you identified someone in #16, do they use their cellular phone to access the internet/applications for your health needs?
18. Do you own a social media account? Please click all that apply.
19. How often do you log into social media networks?
20. What are the barriers to using the Internet/applications on your phone or using social media?
21. Would you be interested in using social media to network with other people with similar health issues?
22. Would you be interested in using a cellphone application to improve your health?
23. If yes to #22, how often would you use it to improve your health?
24. What particular cellphone health application would be useful to you (you may choose more than one)?

- nutrition information
- exercise tracker
- calorie counter
- general health information on chronic diseases
- mental health
- glucose log for diabetes management

25. When you access social media or applications on your cellphone, what is the primary language of the interface?

Demographic Information

Demographic information included age, gender, race/ethnicity, primary language spoken, annual household income, and highest level of education achieved. After the initiation of data collection, it was noted that the income categories used (consistent with other studies and census categories) may not have fully captured the socioeconomic background of our patient population, which has a large proportion of uninsured and undocumented persons. Therefore, a demographic question with regard to education level was added to the final survey after 65 patients had already been interviewed. After this question was added, no further changes were made to the final study survey.

Mobile Phone Usage

Participants were asked if 1) they owned a mobile phone, 2) the mobile phone they owned had Internet capability, and 3) they used the Internet on their mobile phone to learn about their health. Afterwards, the participants were asked about their knowledge of mobile phone apps, if they used such apps, and if they were currently using any mobile health apps. In addition, we asked participants to identify individuals who they might be relying on to use mobile phones and/or mobile apps for them (eg, a partner, child, or friend).

Social Media Usage

We asked participants about current use of social media networks, such as Facebook, Twitter, and Instagram, and to what extent they used these networks.

Interest in Mobile Health Apps and Social Media

Participants were asked if they were interested in using social media to connect with other patients in the same clinic. They were then asked about their interest in using mobile health apps to help improve their health, how often they would use such an app, and what type of app would be most useful to them (eg, obtaining nutrition information, an exercise log, information about chronic diseases).

Participants and Setting

All participants were patients of the 3 primary care clinics staffed by the Internal Medicine residents at LAC+USC Medical Center. In total, LAC+USC Medical Center serves close to 60,000 primary care patients empaneled under the Los Angeles County Department of Human Services. Historically, these clinics have served indigent, uninsured patients of Los Angeles County. Seventy-five percent of the LAC+USC patient population identifies as Hispanic/Latino. With the implementation of the Affordable Care Act, many patients now have state-based exchange health insurance plans. However, these clinics continue to be safety nets, serving undocumented and uninsured patients. Given the nature of these safety net clinics, patients are advised to arrive at least a half hour prior to their scheduled appointment. Patients may wait to be seen for as long as a few hours, which allowed us to recruit a large sample of potential participants.

Survey Delivery

Patients were invited to participate from the general medicine clinic waiting room, and allowed to participate if they had sufficient time to complete the entire survey, solely based on their upcoming appointment time. Bilingual research assistants acquired verbal informed consent and offered assistance to participants while they completed the survey on a provided iPad. Certified medical interpreters were used to interpret the survey (via telephone) for patients whose primary language was not English or Spanish, including Mandarin, Cantonese, and Tagalog. Patients were not provided with remuneration.

Results

A total of 244 adult patients agreed to participate and completed the survey from June 2014 to March 2015. Interviewers reported an average 10% nonparticipation rate among patients with time to complete the survey. Table 1 summarizes the demographic information of the sample. Of these subjects, 234/244 (96%) were under the age of 65, 139/244 (59%) were female, 184/244 (75%) identified themselves as Hispanic or Latino, and 135/244 (55%) identified Spanish as their primary language. Furthermore, 172/217 (79%) reported an annual household income of less than $20,000, 113/178 (63%) had earned at least a high school diploma, and 40/178 (23%) had earned a college or professional degree.

Table 2 highlights the findings regarding mobile phone usage. The great majority of participants (91%, 223/244) owned a mobile phone. Of these 223 subjects, 169 (75%) owned a phone with Internet capability and 136 (72%) used the internet on their phone on a regular basis. Seventy-six percent of Internet phone users reported using the Internet on their mobile phone to search for information regarding their health. The most common websites used to search for health information were 1) Google, 2) WebMD, and 3) YouTube. In terms of mobile phone apps, 67% (160/238) of participants reported knowing the definition of a mobile app. Fifty-seven percent (130/227) reported using apps on their mobile phone, and of these participants, 41/130 (31.5%) used mobile phone apps related to their health. With regard to social media usage, 134/244 (55%) used social media, and 57% (91/160) reported using social media at least once a day. The most common social media platforms reported were Facebook (51%, 125/244) and Twitter (13%, 31/244).

Table 1. Participant demographics (n=244).

Variable		n (%)
Age	18-24	20 (8.2)
	25-34	29 (11.9)
	35-44	48(19.7)
	45-54	75 (30.7)
	55-64	62 (25.4)
	65-74	9 (3.7)
	75+	1 (0.4)
Sex	Female	139 (58.6)
	Male	98 (41.4)
Race/Ethnicity	Mixed Race, Other Race	3 (1.2)
	Asian or Pacific Islander	20 (8.2)
	Black or African American	19 (7.8)
	Hispanic or Latino	184 (75.4)
	White/Caucasian	16 (6.6)
	Prefer not to answer	2 (0.8)
Primary Language	Spanish	135 (55.3)
	English	96 (39.3)
	Mandarin/Cantonese	2 (0.8)
	Tagalog	6 (2.5)
	Other	5 (2.1)
Second Language	English	77 (51)
	Spanish	65 (43)
	Other	10 (6)
Annual Household Income (US dollars, n=217)	< 20,000	172 (79.3)
	20,000-40,000	33 (15.2)
	40,000-60,000	5 (2.3)
	60,000-80,000	4 (1.8)
	80,000-100,000	1 (0.5)
	> 100,000	2 (0.9)
Education Level (n=178)	No schooling	3 (1.7)
	Elementary or Middle School	33 (18.5)
	Some High School	29 (16.3)
	High School Diploma	37 (20.8)
	Some College	36 (20.2)
	College Degree	29 (16.3)
	Masters/Professional	11 (6.2)

Table 2. Mobile phone/Internet usage

Item		n (%)
Do you have a mobile phone?	Yes	223 (91.4)
	Yes, with Internet capability	169 (75.8)
	Yes, without Internet capability	55 (24.7)
	No	21 (8.6)
Do you have a social media account?	Facebook	125 (51.2)
	Twitter	31 (12.7)
	Google Plus	26 (10.7)
	Instagram	44 (18.0)
	Myspace	2 (0.8)
	Other	2 (0.8)
How often do you log into social media networks?	Less than a few times a month	34 (21.3)
	A few times a month	15 (9.4)
	A few times a week	20 (12.5)
	About once a day	44 (29.4)
	More than once a day	47 (27.5)
When you access social media or apps on your mobile phone, what is the primary language of the interface?	Spanish	107 (49.3)
	English	110 (50.7)
Do you know the definition of a mobile phone "App?"	Yes	160 (67.2)
	No	71 (29.8)
	Not sure	7 (2.9)
Do you use apps on your mobile phone?	Yes	130 (57.3)
	Yes, and use health-related apps	41 (31.5)
	No	97 (42.7)
If you use the Internet on your mobile phone for health needs, which sites do you use?	Google	45 (33)
	WebMD	15 (11)
	YouTube	7 (5)
	Yahoo/Bing/Other Search Engine	3 (2)
	Mayo Clinic/PubMed/NIH	2 (1)
	Other	7 (5)

Table 3. Interest in health apps/social media.

Item		n (%)
Would you be interested in using a mobile phone app to improve your health?	Yes	207 (85.9)
	No	34 (14.1)
If you are interested in using a health app, how often would you use it to improve your health?	Every day	88 (39.8)
	Every week	83 (37.6)
	Every month	30 (13.6)
	Every 2-3 months	6 (2.7)
	Not at all	14 (6.3)
What particular health app would be useful to you?	Sugar log for diabetes	84 (34.4)
	Nutrition information	134 (54.9)
	Calorie counter	81 (33.2)
	Exercise log/tips	107 (43.9)
	Mental wellness	62 (25.4)
	General information about diseases	130 (53.3)
	Other	23 (9.4)
Would you be interested in using social media to network with other people with similar health issues?	Yes	168 (70.3)
	No	71 (29.7)

Table 3 highlights the findings from the assessment of subjects interested in using mobile health technology and social media. A total of 207/241 (86%) participants were interested in using a mobile phone app to improve their health, and 40% (88/207) participants stated they would use such an app on a daily basis. These participants most often expressed an interest in using a mobile health app that allowed them to search for general information about various medical conditions as well as exercise logging and nutrition information. In addition, 70% (168/239) of participants stated they would use a social media network to connect with other patients who had similar health problems.

In order to explore predictors of social media and mobile phone app engagement, we examined patients' current use of these platforms. Adjustments were made for broad, commonly used demographic factors that we felt may have influenced mobile phone use. In a multivariate logistic regression model adjusted for phone language, ethnicity, age, income, sex, and education (Table 4), having a phone interface in Spanish was associated with 63% reduced odds of using social media (95% CI 0.14-0.94), and 85% decreased odds of using health-related apps (95% CI 0.03-0.68). Participants under 55 years old were nearly three times more likely to use social media (OR 2.43, 95% CI 1.05-5.66) but were not significantly more likely to use health apps. No significant interaction was found between phone language and ethnicity.

Table 4. Multivariate models to predict health app and social media use among participants with mobile phones.

Model Outcome		OR	95% CI
Use Health Apps (n=120)	Phone language (Spanish vs English)	0.15	(0.03-0.68)
	Hispanic, yes or no	0.86	(0.30-2.43)
	Age under 55	1.37	(0.43-4.34)
	Income under $20,000	1.26	(0.41-3.90)
	Sex	0.46	(0.17-1.17)
	High school degree or above	0.81	(0.19-3.37)
Social Media Use (n=154)	Phone language (Spanish vs English)	0.37	(0.14-0.94)
	Hispanic, yes or no	0.50	(0.17-1.49)
	Age under 55	2.43	(1.05-5.66)
	Income under $20,000	0.95	(0.38-2.38)
	Sex	0.55	(0.26-1.14)
	High school degree or above	1.23	(0.50-3.01)

Discussion

Our study highlights several important findings that have implications with regard to improving the health of patient populations that historically have suffered from health disparities. We found that the vast majority of our primary care clinic patients, despite being of lower socioeconomic status and coming from diverse cultural and linguistic backgrounds, owned mobile phones with advanced Internet and mobile app capabilities. These findings are consistent with several studies that have found an increased use of mobile phones with Internet capability among populations of great cultural, educational, linguistic, and economic diversity [1,7-8]. Furthermore, specific populations, such as Americans with low household incomes and education levels, nonwhites, and females, are much more dependent on mobile phones for accessing the Internet to search for information regarding their health [8-10]. In our population, we found that 41/165 (25%) participants responding to questions about app use endorsed using mobile health apps compared to 19% nationally [1]. Given this comparable usage of mobile internet technology by these groups, further development of culturally and linguistically relevant mobile health apps should be pursued.

A majority of study participants relied primarily on search engines such as Google and Yahoo to search for topics or certain health questions related to their own health. This appeared to be the simplest method of initiating an Internet search on specific health issues for our patients. In addition, a few participants identified YouTube as an effective tool for learning about their health. One subject in particular found that the visual/audio features were useful for learning about health topics, and watching such videos made her feel like she was receiving individualized education about that specific health topic. Prior research has shown that visual aids are effective methods of educating patients of lower health literacy [11,12], and the addition of audio instruction may be even more beneficial to patients with limited educational backgrounds. Although this was not a particular focus of our study, this does provide an opportunity for future research to assess the interest and use of online instructional and educational health videos by medically underserved patients.

Over half of participants who owned a mobile phone in our study reported regular use of mobile phone apps. Thirty-one percent of these participants actually used apps related to their own health management. These findings reflect a rise in mobile health app usage among ethnically diverse populations; in 2014, only 15% of Hispanics reported use of health-related mobile phone apps [2]. It is becoming apparent that these culturally diverse patient populations are realizing the utility of mobile health apps in helping to manage their own health.

In general, a great majority of our study participants (86%, 207/241) stated they were interested in using a mobile health app to learn more about their health and how to manage their chronic diseases. Further, our patients reported they would use such an app on a regular basis, showing that patients were interested in taking initiative to monitor their own health. Most patients were interested in tools that would help educate them about chronic diseases and good nutrition, and in monitoring and advice tools regarding physical activity. Mobile health technology could address barriers to health care that these groups face, including language barriers preventing health education as well as limited access to care due to lack of resources in safety net clinics [13]. Patients reported that they would prefer to use apps in their primary language (Spanish being the language most often identified). Our study shows that there is a high demand for development of such technology and efforts should aim to provide these particular patients with these tools.

In addition to using mobile health apps, a large number of patients reported interest in using a social media network to connect with other patients if this resource were made available. Prior research has shown how social networks, such as Facebook and Twitter, have been effective in improving outcomes in patients with chronic diseases such as HIV/AIDS, breast cancer, and chronic tobacco use [14-16]. These studies have shown that patients using social media networks are willing to share their health information in order to educate others about disease awareness and treatment, as well as to ask questions of other patients who may be suffering from similar symptoms and undergoing similar treatments [17-20]. Our study shows that our diverse clinic patient population is interested in using social networking to meet other patients with similar health issues, which could encourage patients to build a support network for themselves and increase motivation and social support to make positive changes.

In terms of limitations of our study, the number of patients who completed the survey was fairly small. This was, by definition, a convenience sample. However, all efforts were made to recruit as many participants as possible and facilitate completion of the survey with the available interpreters. As mentioned previously in the methods section, a question with regard to education level was not added to the final survey until after 65 patients had already completed the survey. This, and the ability to skip questions, unfortunately resulted in a smaller sample size being used for our secondary analysis (Table 4). However, because all other methodology of the survey collection, including clinic location, survey collection hours, and languages spoken, remained unchanged, we do not feel these patients are substantively different from our study population as a whole. Furthermore, though we assessed current use of mobile health apps, we did not specifically explore ways our patients used social media with regard to their health. Finally, due to the lack of standardized instruments regarding this research topic, we were unable to statistically validate the intervention questions in our survey tool. However, all survey questions were consistent with previously published literature in the field.

Conclusion

Our study explored important issues with regard to *mHealth* use by culturally, linguistically, and educationally diverse patient communities. Though the majority of our primary care patients are of lower socioeconomic status, our patients utilize mobile phones with Internet and mobile app capabilities to a great extent. There is substantial interest among our patients in using mobile health technology, including mobile health apps and social networking resources. Given that cultural, educational,

and socioeconomic disparities strongly correlate with higher rates of chronic diseases such as diabetes and hypertension, access to culturally relevant mobile health tools may help both patients and providers with management of these conditions. More research is needed to investigate the specific health needs of these patient populations in order to guide development of culturally and linguistically tailored mobile health technology.

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Conflicts of Interest

None declared.

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Abbreviations

mHealth: mobile health
LAC+USC: Los Angeles County + University of Southern California

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Original Paper

The Use of Mobile Phone and Medical Apps among General Practitioners in Hangzhou City, Eastern China

Ying Liu[1], MD; Wen Ren[1], MD; Yan Qiu[1], MD; Juanjuan Liu[1], MD; Pei Yin[1], MD; Jingjing Ren[1], MD, PhD

General Practice Department, The First Affiliated Hospital, College of Medicine, Zhejiang University, Hangzhou, China

Corresponding Author:
Jingjing Ren, MD, PhD
General Practice Department, The First Affiliated Hospital
College of Medicine
Zhejiang University
#79 Qingchun Road
Hangzhou, 310003
China
Phone: 86 138 1948 5898
Fax: 86 571 8723 5012
Email: lisarjj@126.com

Abstract

Background: Mobile phones and mobile phone apps have expanded new forms of health professionals' work. There are many studies on the use of mobile phone apps for different specialists. However, there are no studies on the current use of mobile phone apps among general practitioners (GPs).

Objective: The objective of the study was to investigate the extent to which GPs own smartphones with apps and use them to aid their clinical activities.

Methods: A questionnaire survey of GPs was undertaken in Hangzhou, Eastern China. Data probing GPs' current use of medical apps in their clinical activities and factors influencing app use were collected and analyzed

Results: 125 GPs participated in the survey. 90.4% of GPs owned a mobile phone, with 48.7% owning an iPhone and 47.8% owning an Android phone. Most mobile phone owners had 1-3 medical-related apps, with very few owning more than 4. There was no difference in number of apps between iPhone and Android owners (χ^2=1.388, P=0.846). 36% of GPs reported using medical-related apps on a daily basis. The majority of doctors reported using apps to aid clinical activities less than 30 minutes per day.

Conclusions: A high level of mobile phone ownership and usage among GPs was found in this study, but few people chose medical-related apps to support their clinical practice.

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KEYWORDS

mobile phone; app use; general practitioner; mobile technology

Introduction

Mobile phone use has drastically changed the way we work and live. From Internet access to email, it offers on-the-go access to information with unprecedented ease. The ownership of mobile phones by health professionals is increasingly common, and health professionals' use of mobile phone apps has changed how they do their work [1].

Previous literature has examined mobile phone acceptance and medical app usage with medical students, interns, junior doctors, and trainees. For example, Payne et al [2] found a high degree of mobile phone ownership and use among medical students and junior doctors. They endorsed the development of more apps to support education and clinical practice. One study showed that urology trainees in Ireland found mobile phones to be a useful aid in clinical practice both as an educational and reference tool [3]. Another study revealed that 85% of medical providers working in Accreditation Council for Graduate Medical Education (ACGME) training programs reported use of mobile phones [4]. Mobile phone usage was also widespread among interns in Ireland university hospitals, where apps could aid clinical practice and education [5]. Rung et al studied mobile phone use in Australian dental students, and concluded that

students used mobile phones for their education although the technology had not been formally included in the curriculum [6].

Mobile phones with medical apps have been demonstrated to be very useful for medical students and physicians. However, there are no studies on the current use of apps among general practitioners (GPs). GPs, known as the gatekeepers of health care, are doctors who treat acute and chronic illnesses and provide preventive care and health education irrespective of age and sex. Though GPs comprise a small proportion of all doctors in China (5.6%), they readily take on the role of health gatekeepers [7]. GPs who work in community health centers (CHCs) provide *Six in One* services for Chinese residents. *Six in One* services include preventive care, health care, medical care, rehabilitation, health education and family planning technology guidance, and all 6 services are provided by GP-centered primary care teams. Studies showed that mobile phones and apps can be useful for patient education, remote patient monitoring, mobile clinical communication, disease management and so on [8-10], and could thus support general practices. In this study, we conducted a survey on mobile phone usage among GPs in a city located in eastern China.

The objectives of this study were (1) to identify the extent to which GPs own mobile phones and which types, (2) to evaluate how often they use apps to acquire medical information and support clinical decisions, and (3) to investigate the types and frequency of apps used. This study provides a preliminary glimpse into a cross-sectional study on mobile phone ownership and usage among GPs in eastern China.

Methods

A cross-sectional study was designed and conducted from October to December 2014 in Hangzhou city, the capital of Zhejiang Province, Eastern China. Hangzhou has a population of 8.8 million and is ranked tenth in terms of gross domestic product per capita among China's 100 major cities.

Six CHCs were randomly selected from the six main districts of Hangzhou city. All the GPs who were working in these centers (defined as having had acquired a medical license and finished 1-3 years GP training) completed a questionnaire on paper. The study was approved by the ethics committee of the First Affiliated Hospital, College of Medicine, Zhejiang University.

The questionnaire and definitions of medical apps used in the survey were derived from a similar study conducted in the UK [2]. To ensure the validity of the questionnaire, an expert panel (6 doctors having at least 5 years' experience in general practice or primary care research) was invited to review and revise it. The questionnaire was then piloted within one CHC and altered accordingly. The final questionnaire was composed of 5 questions probing the GPs' current use of medical apps in their clinical activities and influencing factors, including: the number who owned a mobile phone; type of mobile phone; the number of medical apps owned; how often medical apps were actually referred to during working hours; and the clinical environment in which non-medical mobile phone apps were used. The number of medical apps they owned was determined by how many of these apps were on their mobile phone during the study. Medical apps were divided into the following categories: literature search tools, disease diagnosis/management apps, medical calculators, and drug reference apps [1-2].

All numerical data were managed and analyzed by the Statistical Package for Social Sciences (SPSS Inc.). Initial descriptive statistics were determined and the Chi-square test was used for inferential analyses.

Results

A total of 125 GPs working in 6 CHCs participated in the survey; the respondent rate was 100%. The male to female split was 45.6% (57/125) and 54.4% (68/125) respectively. The mean age of participants was 36.2 years (SD 6.9) with a range of 25 to 60 years, while 61 GPs were younger than 35 years. Regarding the educational level, 106 participants had a bachelor degree and above. 118 participants had been involved in the GP training program, while only 26 participants took part in the Medical Information Program.

Regarding working experience, 92 participants had been working in General Practice for more than 5 years. In China, a medical doctor's professorial equivalent is expressed in 5 levels (from senior to junior), which are: (1) chief doctor (equivalent to professor grade in universities), (2) associate chief doctor (equivalent to associate professor grade in universities), (3) attending specialist (equivalent to lecturer grade in universities), (4) resident (acquired a bachelor degree and works at a stage of postgraduate medical training), and (5) assistant doctor (acquired a three-year medical diploma). With respect to professional grade, 9 participants were chief doctors or associate chief doctors and 78 participants were attending specialists. The monthly income of most GPs (88%, 110/125) varied from US $500 to US $800, while the income range was US $320 to US $1600.

There were 113 participants who owned a mobile phone, 55 with an iPhone, 54 with an Android, and 4 owning other mobile phones. Young participants (under the age of 35) were more likely to own a mobile phone (χ^2=8.705, P=0.013). There were no significant association with gender, education, title, time of working in General Practice, income and GP training program.

The number of medical apps installed by GPs is displayed in Table 1. 75 mobile phone owners had medical apps. Among them, 39 were iPhone owners, 39 had Android phones and 4 users had 'other' mobile phones. There was no difference between iPhone and Android users who own apps (χ^2=1.4, P=0.846). 32 mobile phone users reported downloading 1 medical app on their mobile phone, 21 downloaded 2 apps, 12 downloaded 3 apps, 10 downloaded 4-15, and 38 users reported having no medical apps on their mobile phone.

Table 2 shows the frequency of medical apps used by GPs. Among these 75 mobile phone users who have downloaded medical apps, 27 GPs reported using them on a daily basis, 24 GPs on a weekly basis while 18 reported rarely using them and 6 GPs never used these apps.

Table 3 shows the time GPs used medical apps on a daily basis to aid clinical activities. 27 GPs responded that they used medical apps every day. However, 25 GPs used medical apps to aid clinical activities less than 30 minutes a day.

Table 1. Number of medical apps installed by GPs.

		Total (N=113)	iPhone users (n=55)	Android users (n=54)	Others (n=4)
Own medical apps					
	No	33.6% (38/113)	29.1% (16/55)	37.0% (20/54)	50.0% (2/4)
	1 app	28.3% (32/113)	32.7% (18/55)	25.9% (14/54)	0 (0)
	2 apps	18.6 % (21/113)	16.4% (9/55)	18.5% (10/54)	50.0% (2/4)
	3 apps	10.6% (12/113)	10.9% (6/55)	11.1% (6/54)	0 (0)
	4-15 apps	8.9% (10/113)	10.9% (6/55)	7.5% (4/54)	0 (0)

Table 2. Frequency of medical apps used by GPs.

Frequency of use	Percentage who used (n=75)
Daily	36% (27/75)
Weekly	32% (24/75)
Rarely	24% (18/75)
Never used	8% (6/75)

Table 3. Daily use, in minutes, of GPs' medical app use for clinical activities.

Daily use of apps	Percentage who used (n=27)
None	4% (1/27)
1-10 minutes	26% (7/27)
11-20 minutes	37% (10/27)
21-30 minutes	26% (7/27)
> 31 minutes	7% (2/27)

Figure 1. Type of medical app and frequency of use by GPs.

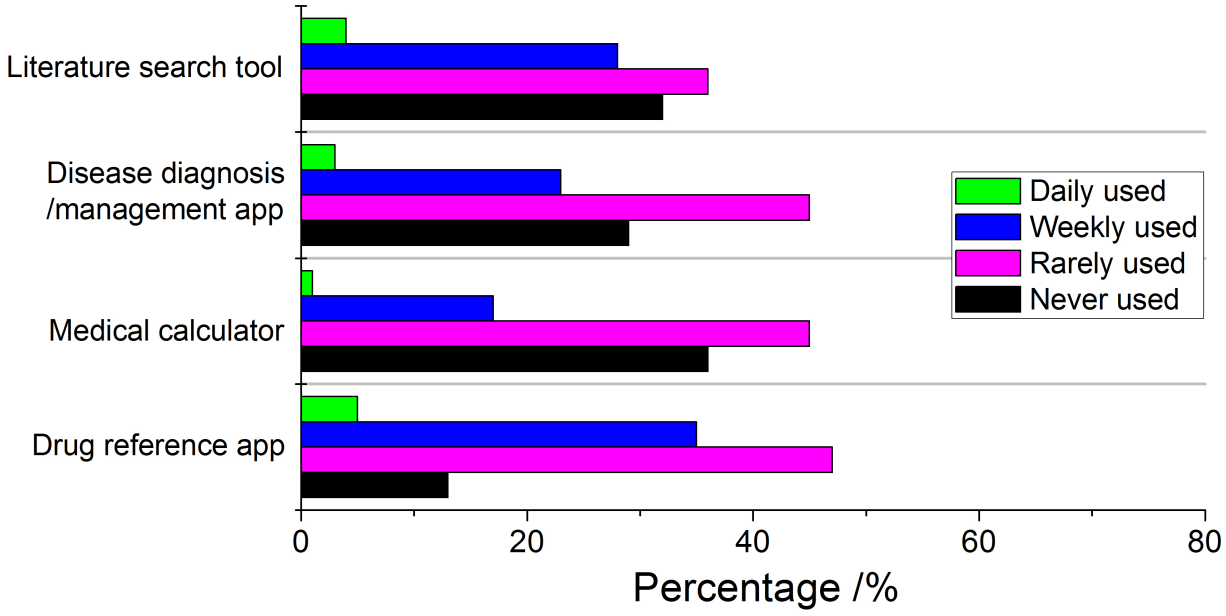
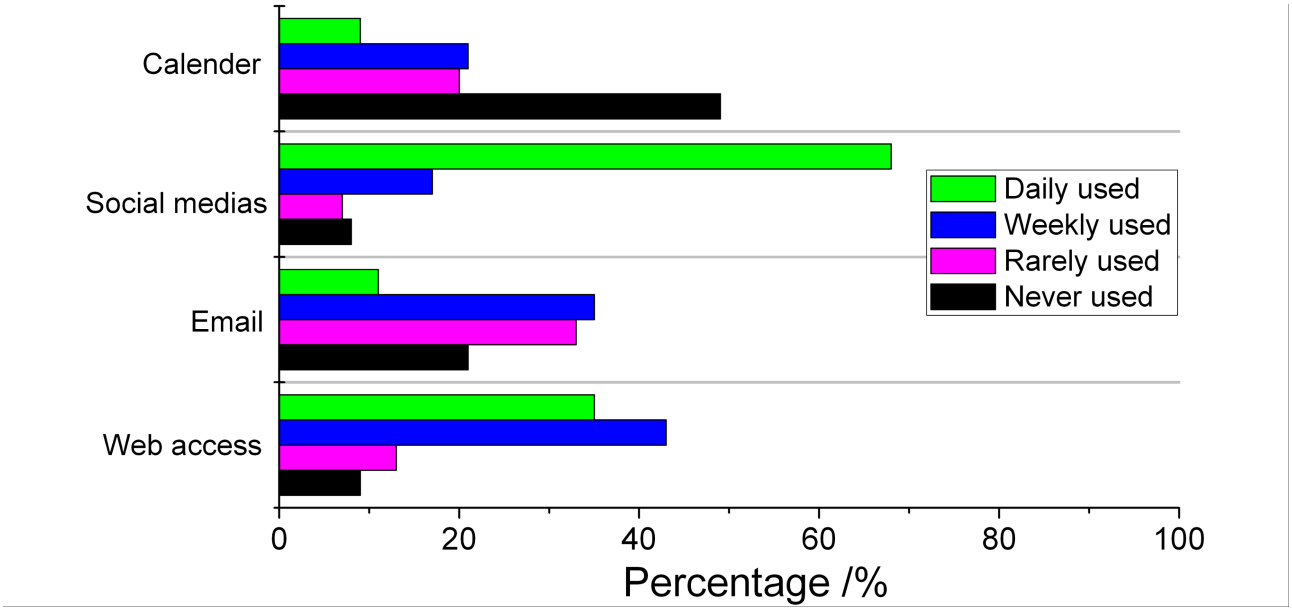


Figure 2. Type of non-medical app and frequency of use by GPs.



Figures 1 and 2 show the type of medical and non-medical apps used by GPs, and how often these were used. According to these two figures, they used non-medical apps much more frequently than medical apps. The most frequent type of medical app used was drug reference apps; non-medical apps were most frequently social media apps.

Discussion

Overview

This study is the first formal survey to investigate mobile phone ownership and usage among GPs in China. The result of our study demonstrates that a substantial proportion (90.4%) of GPs use mobile phones, with no difference based on income level or professional grades (Table 1). Previously, in the UK, a regional survey conducted on mobile phone-based healthcare apps usage by Payne et al [2] in 2011 found 74.8% of junior doctors owned a mobile phone (n=601). In the US, a nation-wide email survey of all the ACGME training programs (N=3,306) revealed that 85% of respondents used a mobile phone [4]. In Ireland, a voluntary novel questionnaire survey revealed that, among interns in two university hospitals, 98.4% owned a mobile phone [5]. Though the income for GPs in China is lower than Western countries, the percent of mobile phone ownership is higher than the UK and the US, and lower than Ireland. It should be pointed out that the surveys in UK and US were conducted before 2012, when mobile phones were not so widespread. An investigation from Google and IPSOS in 2013 revealed that mobile phone penetration is currently at 47% of the population in China [11]. Our research shows that mobile phone ownership among GPs in eastern China is higher than that of the general public. The common feature of previously-mentioned studies is that the selected subjects were young doctors, while in this study GPs at every age level were

included. The extreme popularity of mobile phones among all ages demonstrates how well-accepted mobile phones are among Chinese GPs. When examining the differences between ages, our survey suggested that young GPs (under 35 years) are more likely to embrace mobile phones, perhaps due to the fact that they are more "technologically adept" [2].

In our survey, 66.4% of mobile phone users reported downloading medical apps, 86.7% of whom own 1-3 such apps (Table 1). In the UK, 75.5% of mobile phone user used medical apps among junior doctors, and the majority (51%) of them owned 1 to 5 medical apps [2]. In the US, 63.5% of doctors used medical apps [4]. In Ireland, 77% of urology trainees [3] and 91.6% of interns [5] downloaded apps. With these intern mobile phone users, 53.3% reported downloading between 1 and 3 medical apps [5]. Research from all these countries show that the majority of doctors download few medical apps, perhaps due to the cost of apps and Internet connections, limited working time, the capacity of their mobile phones, and high workload [2,12].

In Table 2, we see that 36% of GPs report using medical apps on a daily basis. In Table 3, the majority of doctors report using medical apps daily less than 30 minutes to aid the clinical activities. Compared with other surveys, these results are higher than junior doctors in the UK, but lower than interns in Ireland. In the UK, 29.6% of junior doctors reported using apps on a daily basis and most of them using apps less than 30 minutes per day [2]. In Ireland, 43.6 % interns report using them on a daily basis [5]. This suggests that doctors are using apps as a source of quick references [2], and the conclusion could be drawn that convenience and speed are the main reasons for doctors choosing apps.

When we try to investigate which kinds of apps for GPs were used frequently, interestingly, we found that non-medical apps were used much more frequently to aid their medical activity than medical apps during working hours, as shown in Figure 1 and 2. 67% of GPs use social media apps every day to support clinical activities. Most of the clinical activities included reading case-related essays, as reported by the respondents. Web browsers were the second most popular type of app (34% report daily use) which GPs use to search medical knowledge. By contrast, the most frequently used type of medical app–drug reference apps–only have 5% daily users. This remarkable contrast can be attributed to 2 reasons. First of all, the apps' function cannot meet their needs [4]. Some respondents in our survey told the investigator that using apps to aid clinical activities is waste of time and they did not have time to use them. Secondly, while medical apps have very specialized applications, non-medical apps provide more diverse functions. For instance, social media can provide an online community where doctors can read articles, listen to experts, find new medical research results, and communicate with colleagues and patients [13]. On the other hand, most medical apps have limited function, and as a result, their acceptance is not as high as non-medical apps.

With medical apps, the most frequently used in China are for drug reference, while social media is the most popular type of non-medical app. In contrast, junior doctors in the UK used clinical scoring apps more often [2]. There are two possible explanations for this. First of all, in Chinese hospitals, there are many traditional Chinese medicines, and different hospitals own different medicines from various companies, resulting in a complex pharmaceutical system. Moreover, patients may approach GPs with prescriptions received from other hospitals. As such, GPs have to constantly update their knowledge about different kinds of medicines. Secondly, in China, most GPs take care of their patients based on their own experiences rather than evidence-based medicine, and they rarely use clinical scoring apps to aid their work.

Limitations

This study only focuses on GPs who are working in CHCs located in one city, and those working in various levels of hospitals are not involved. Thus the study cannot speak to circumstances for GPs in other areas of China. In addition, since no psychometric properties of the questionnaire are explored, the reliability of the instrument is unknown.

Conclusions

This study shows that mobile phones are popular among GPs in eastern China. Though the frequency of medical app use by GPs is similar with doctors in other countries, few GPs choose medical apps to support their clinical practice. Due to the behavioral habits of these GPs and the narrow usage of specific medical apps, non-medical apps such as social media were more frequently used to aid their medical activity during working hours. Mobile phones can be useful for many aspects of general practice, such as patient care, health education, and professional communication. However, all these functions have not been widely used by Chinese GPs, which needs to be explored in the future; apps especially designed for GPs with these specific functions are expected for future development.

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Authors' Contributions

YL conducted the research, analyzed the data, and drafted the first version of the manuscript. JR, WR and PY contributed to the conception and design of the study. YQ and JL contributed to writing and editing the manuscript. JR had primary responsibility for the final content of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ACGME: Accreditation Council for Graduate Medical Education
CHC: community health center
GP: general practitioner

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Original Paper

Mobile Phone Use and its Association With Sitting Time and Meeting Physical Activity Recommendations in a Mexican American Cohort

Matthew Chrisman[1], PhD (Public Health); Wong-Ho Chow[1], PhD; Carrie R Daniel[1], PhD; Xifeng Wu[1], MD, PhD; Hua Zhao[1], PhD

The University of Texas MD Anderson Cancer Center, Department of Epidemiology, Houston, TX, United States

Corresponding Author:
Matthew Chrisman, PhD (Public Health)
The University of Texas MD Anderson Cancer Center
Department of Epidemiology
1155 Pressler St., Unit 1340
Houston, TX, 77030
United States
Phone: 1 713 792 0496
Fax: 1 713 794 1964
Email: mchrisman@mdanderson.org

Abstract

Background: The benefits of physical activity (PA) are well-documented. Mobile phones influence PA by promoting screen-based sedentary time, providing prompts or reminders to be active, aiding in tracking and monitoring PA, or providing entertainment during PA. It is not known how mobile phone use is associated with PA and sitting time in Mexican Americans, and how mobile phone users may differ from nonusers.

Objective: To determine the associations between mobile phone use, PA, and sitting time and how these behaviors differ from mobile phone nonusers in a sample of 2982 Mexican-American adults from the Mano a Mano cohort.

Methods: Differences in meeting PA recommendations and sitting time between mobile phone users and nonusers were examined using chi-square and analysis of variance tests. Logistic regression was used to examine associations between mobile phone use, PA, and sitting.

Results: Mobile phone users were more likely to be obese by body mass index criteria (≥30 kg/m^2), younger, born in the United States and lived there longer, more educated, and sit more hours per day but more likely to meet PA recommendations than nonusers. Males (odds ratio [OR] 1.42, 95% CI 1.16-1.74), use of text messaging (OR 1.26, 95% CI 1.03-1.56), and having a higher acculturation score (OR 1.27, 95% CI 1.07-1.52) were associated with higher odds of meeting PA recommendations. Sitting more hours per day was associated with being male, obese, born in the United States, a former alcohol drinker, and having at least a high school education. Among nonusers, being born in the United States was associated with higher odds of more sitting time, and being married was associated with higher odds of meeting PA recommendations.

Conclusions: Mobile phone interventions using text messages could be tailored to promote PA in less acculturated and female Mexican American mobile phone users.

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KEYWORDS

mobile phone; physical activity; Mexican Americans; sedentary lifestyle

Introduction

The importance of physical activity (PA) for health is well-documented [1], yet evidence shows that Hispanic people in the United States have higher rates of inactivity than other ethnicities and are less likely to meet US national PA recommendations [2]. Additionally, increasing evidence suggests that more time spent sitting leads to detrimental health effects [3], thus interventions are needed to increase PA and reduce sitting time.

Mobile phone interventions are one potential avenue for promoting activity and reducing sitting [4,5]. Mobile devices have become ubiquitous, with 6.7 billion mobile phone subscriptions worldwide at the beginning of 2014 [6]. As of 2012, mobile phone ownership among US Hispanic adults was 86%, a proportion similar to non-Hispanic whites (84%) and blacks (90%) [7]. The small size and ease of use of mobile devices mean they can be carried anywhere and ultimately may influence behavior through sedentary "screen time," while texting, emailing, or playing games, or using the devices while standing or participating in moderate activity [8]. They can also provide an impetus for being active through apps that provide reminders or prompts for participating in PA and may aid in tracking and monitoring amounts of activity one engages in, particularly because they were designed to be used while being mobile [8].

Several recent reviews have showed the value in using mobile phones in PA interventions [9,10]. In particular, studies using mobile phones reported increases in PA and reductions in inactivity in a variety of settings and populations [9,10]. However, to prepare for such an intervention, it is helpful to know the extent of any group differences between mobile phone users and nonusers and what associations, if any, exist between mobile phone use and activity behaviors. The relationships between mobile phone use, PA, and sitting time have not been well-described, particularly among Hispanic people in the United States. To better understand PA and sitting time, mobile phone use appears to be a variable worthy of exploring in this population [8]. Additionally, considering that mobile phone owners are more likely to be younger, be college graduates, and have a higher income [11], there may be important behavioral or sociodemographic differences that affect health between users and nonusers of mobile phones.

Hispanic people in the United States are predominantly of Mexican descent [12], and knowing more about their PA and sitting time behaviors may be informative for this group as a whole. The Mexican American Mano a Mano Cohort study is a population-based study of more than 25,000 participants of Mexican origin who have provided data on their activity and sitting behavior, including a subset of participants who have offered data on their usage of mobile phone devices. Because this population has a high rate of mobile phone ownership, this cohort provides an opportunity to examine relationships among these factors. This study's purpose was therefore to determine the associations between mobile phone use, PA, and sitting time and how these behaviors differ from mobile phone nonusers in a sample of urban-dwelling Mexican American adults from the Mano a Mano cohort. To our knowledge, ours is the first report to examine these associations in this population. Findings can be used to tailor future interventions in this area.

Methods

Recruitment

Mano a Mano is an ongoing prospective study examining cancer and chronic disease risk factors in adults residing in the Houston metropolitan area of Texas. Details of this cohort are described elsewhere [13]. Briefly, the study was initiated in 2001 and currently enrolls more than 25,000 adults of Mexican origin. The mean age is 40.8 years (SD 14.2), 73.7% were born in Mexico, and 79.3% are female. Data collection spans a range of social and health characteristics, and trained interviewers administer questionnaires at the participants' homes in their preferred language (English or Spanish). This study used a subset of the overall Mano a Mano cohort. Participants providing data for this study were recruited beginning in 2012, when questions on media use, including mobile phones, were first asked. The institutional review board at The University of Texas MD Anderson Cancer Center approved all study procedures.

Data

Sociodemographic characteristics assessed at baseline include age, sex, marital status, education, birthplace (Mexico or United States), body mass index (BMI), acculturation, alcohol drinking and smoking status (current, former, and never), and years lived in the United States. Age was grouped into categories of 21-39, 40-54, and 55+ years to account for the potential nonlinear relationship with PA [14]. Marital status was categorized as married or not married, and education was categorized as some high school or less or high school graduate and beyond. Body mass index was calculated from measured height and weight and participants were categorized as obese (BMI $\geq$ 30 kg/m^2) or not obese (BMI <30 kg/m^2). Degree of acculturation was assessed using the Bidimensional Acculturation Scale for Hispanics [15], which measures linguistic preference when speaking, watching television, listening to the radio, and reading. Responses ranged from 1-4 and were dichotomized into low ($\leq$2) or high (>2), with high values reflecting a preference for and fluency in English and a high degree of acculturation. This variable was dichotomized to maintain consistency with other reports using this cohort [16,17].

Physical activity was assessed using the International Physical Activity Questionnaire (IPAQ) short form, which has been validated in multiple populations and exhibits acceptable reliability in Mexican Americans [18,19]. The IPAQ measures activity bouts of at least 10 minutes by domain (work, home, transportation, and recreation) in the past week, and PA is classified by intensity (vigorous, moderate, walking) [20]. Vigorous and moderate activity were used to calculate whether the participants met the US national PA recommendations, which state that individuals should engage in 150 minutes of at least moderate-intensity activity each week, with 1 minute of vigorous PA considered equivalent to 2 minutes of moderate PA [1]. A single item on the IPAQ assessed time spent sitting on a normal weekday in the past 7 days, which exhibits acceptable reliability in adults [21]. Sitting time was dichotomized into 0-3 hours per day and greater than 3 hours per day, which was done to maintain consistency with other reports in the literature [16,22].

Media use was assessed by asking whether participants use a mobile phone; if they use it for playing music, sending text messages, accessing the Internet, social media use, and sending and receiving email; and how often they use it for those functions.

Statistical Analysis

Physical activity and sitting data were computed according to published guidelines [20]. Descriptive statistics were examined for all variables, and differences between mobile phone users and mobile phone nonusers were examined using chi-square and analysis of variance tests. Analyses were stratified based on the a priori hypothesis that mobile phone users and nonusers are different. Unadjusted odds ratios were calculated for PA and sitting time among each sociodemographic variable for mobile phone users and nonusers separately. Multivariate logistic regressions were then conducted to examine odds of meeting US PA recommendations and sitting 3 or more hours per day, controlling for factors that were significant in univariate analyses. All analyses were conducted using SPSS version 22 (IBM Corp., Armonk, NY), and a 2-sided *P* value of .05 was considered statistically significant.

Results

Overall, there were 2892 participants, of whom 2556 (88.4%) reported using a mobile phone. Compared with nonusers, mobile phone users were more likely to be obese, younger, born in the United States, more educated, more acculturated, meet US PA recommendations but also sit more than 3 hours per day, and live longer in the United States (Table 1). Data on media use types had high percentages of missing data, as follows: playing music (70.5% missing), accessing the Internet (57.7% missing), social media use (73.0% missing), and sending and receiving email (75.2% missing). Thus, these data were not included in regression analyses.

Tables 2 and 3 show the odds of meeting PA recommendations and for sitting more than 3 hours per day among mobile phone users and nonusers separately. Among both mobile phone users and nonusers, more variables were associated with time spent sitting than with meeting PA recommendations. For mobile phone users, younger age, males, higher education, having a high acculturation score, being a current alcohol drinker, and use of text messaging were associated with meeting PA recommendations; whereas, males, born in the United States, not married, higher education, being obese, having a high acculturation score, current or former alcohol drinker, current or former smoker, and use of text messaging were associated with sitting 3 or more hours per day. For mobile phone nonusers, only being married was associated with meeting PA recommendations; whereas, being male, born in the United States, more educated, having a high acculturation score, and current or former smoker were associated with sitting 3 or more hours per day.

After adjustment for factors associated with PA and sitting time, meeting US PA recommendations among mobile phone users was associated with being male (odds ratio [OR] 1.42, 95% CI 1.16-1.74), texting (OR 1.26, 95% CI 1.03-1.56), and having a higher acculturation score (OR 1.27, 95% CI 1.07-1.52), and it was inversely associated with being a former alcohol drinker (OR 0.71, 95% CI 0.57-0.87; Table 4). Sitting 3 or more hours per day among mobile phone users was associated with being male (OR 1.26, 95% CI 1.02-1.56), obese (OR 1.30, 95% CI 1.11-1.54), born in the United States (OR 2.08, 95% CI 1.64-2.62), higher education (OR 1.51, 95% CI 1.26-1.82), and being a former alcohol drinker (OR 1.48, 95% CI 1.12-1.95; Table 4). For mobile phone nonusers, being married (OR 2.01, 95% CI 1.09-3.68) was associated with meeting US PA recommendations, and sitting 3 or more hours per day was associated only with being born in the United States (OR 2.56, 95% CI 1.05-6.21; Table 5).

Table 1. Comparing mobile phone users (n=2556) with mobile phone nonusers (n=328) in the Mexican American Mano a Mano cohort.

Variable	Mobile phone users, N (%)	Mobile phone nonusers, N (%)	*P* value
Age, years			
21-39	651 (25.5)	44 (13.4)	<.001
40-54	1142 (44.7)	119 (36.3)	
55+	763 (29.9)	165 (50.3)	
Sex			
Male	738 (28.9)	85 (25.9)	.264
Female	1818 (71.1)	243 (74.1)	
Birthplace			
Mexico	1977 (77.4)	286 (87.2)	<.001
United States	576 (22.6)	42 (12.8)	
Marital status			
Not married	646 (25.3)	79 (24.1)	.638
Married	1909 (74.7)	249 (75.9)	
Education			
Some high school or less	1583 (62.0)	257 (78.4)	<.001
High school graduate	972 (38.0)	71 (21.6)	
Obesity			
Not obese	1170 (46.8)	167 (53.4)	.029
Obese	1330 (53.2)	146 (46.6)	
Acculturation			
Low	1277 (50.0)	239 (72.9)	<.001
High	1279 (50.0)	89 (27.1)	
Alcohol drinking status			
Current	597 (23.4)	53 (16.2)	.016
Former	337 (13.2)	44 (13.4)	
Never	1622 (63.5)	231 (70.4)	
Smoking status			
Current	311 (12.2)	31 (9.5)	.313
Former	472 (18.5)	51 (15.6)	
Never	1772 (69.3)	245 (47.9)	
Use text messaging			
Yes	1804 (70.6)	---	---
No	749 (29.3)	---	
Physical activity recommendations			
Not meeting	1583 (61.9)	228 (69.5)	.008
Meeting	973 (38.1)	100 (30.5)	
Sitting 3 or more hours/day			
Yes	1296 (50.7)	191 (58.2)	.011
No	1259 (49.3)	137 (41.8)	

Table 2. Unadjusted odds ratios (95% CI) for mobile phone users for meeting physical activity recommendations and sitting 3 or more hours per day (n=2556).

Variable	Meeting PA[a] recommendations		Sitting 3+ hours/day	
	OR[b]	95% CI	OR	95% CI
Age				
Age 21-39 years	1.00		1.00	
Age 40-54 years	0.82	0.68-0.99	0.85	0.70-1.02
Age 55+ years	0.65	0.53-0.79	0.98	0.81-1.20
Gender				
Female	1.00		1.00	
Male	1.49	1.25-1.77	1.38	1.16-1.64
Country of origin				
Mexico-born	1.00		1.00	
US-born	1.04	0.86-1.27	2.74	2.25-3.33
Marital status				
Not married	1.00		1.00	
Married	1.13	0.94-1.36	0.84	0.70-0.99
Education				
Some HS[c] or less	1.00		1.00	
HS graduate	1.21	1.03-1.43	1.85	1.57-2.17
Weight status				
Not obese	1.00		1.00	
Obese	0.88	0.75-1.04	1.36	1.16-1.60
Acculturation status				
Low acculturation	1.00		1.00	
High acculturation	1.42	1.21-1.66	1.81	1.55-2.12
Alcohol status				
Never drinker	1.00		1.00	
Former drinker	0.93	0.73-1.20	1.79	1.41-2.27
Current drinker	1.76	1.46-2.13	1.60	1.33-1.94
Smoking status				
Never smoker	1.00		1.00	
Former smoker	1.06	0.86-1.31	1.31	1.07-1.60
Current smoker	1.25	0.98-1.60	1.77	1.39-2.27
Text messaging				
Do not use text messaging	1.00		1.00	
Use text messaging	1.39	1.16-1.66	1.31	1.10-1.55

[a]PA: physical activity.

[a]OR: odds ratio.

[a]HS: high school.

Table 3. Unadjusted odds ratios (95% CI) for mobile phone nonusers for meeting physical activity recommendations and sitting 3 or more hours per day (n=328).

Variable	Meeting PA[a] recommendations		Sitting 3+ hours/day	
	OR[b]	95% CI	OR	95% CI
Age				
Age 21-39 years	1.00		1.00	
Age 40-54 years	1.03	0.50-2.11	1.15	0.57-2.34
Age 55+ years	0.56	0.28-1.14	1.17	0.59-2.31
Gender				
Female	1.00		1.00	
Male	1.17	0.69-1.98	2.10	1.28-3.47
Country of origin				
Mexico-born	1.00		1.00	
US-born	0.90	0.44-1.84	4.18	2.05-8.52
Marital status				
Not married	1.00		1.00	
Married	2.01	1.09-3.68	0.62	0.37-1.04
Education				
Some HS[c] or less	1.00		1.00	
HS graduate	1.55	0.89-2.68	1.84	1.08-3.12
Weight status				
Not obese	1.00		1.00	
Obese	1.18	0.73-1.91	1.02	0.65-1.60
Acculturation status				
Low acculturation	1.00		1.00	
High acculturation	1.41	0.84-2.37	2.55	1.55-4.19
Alcohol status				
Never drinker	1.00		1.00	
Former drinker	1.03	0.51-2.08	0.40	0.20-0.77
Current drinker	1.48	0.80-2.77	0.96	0.52-1.76
Smoking status				
Never smoker	1.00		1.00	
Former smoker	0.89	0.46-1.73	2.31	1.25-4.26
Current smoker	0.62	0.26-1.51	2.43	1.14-5.19

[a]PA: physical activity.

[a]OR: odds ratio.

[a]HS: high school.

Table 4. Multivariate adjusted odds ratios (95% CI) of mobile phone users for meeting physical activity recommendations and sitting 3 or more hours/day.

Variable	OR[a]	95% CI
Meeting PA[b] recommendations		
Age 21-39 years	1.00	
Age 40-54 years	0.83	0.65-1.05
Age 55+ years	0.90	0.73-1.11
Female	1.00	
Male	1.42	1.16-1.74
Low acculturation	1.00	
High acculturation	1.27	1.07-1.52
Never alcohol drinker	1.00	
Former drinker	0.71	0.57-0.87
Current drinker	1.27	0.97-1.67
Do not use texting	1.00	
Use texting	1.26	1.03-1.56
Sitting 3 or more hours/day		
Female	1.00	
Male	1.26	1.02-1.56
Less than HS[c]	1.00	
HS graduate and beyond	1.51	1.26-1.82
Mexico-born	1.00	
US-born	2.08	1.64-2.62
Not married	1.00	
Married	0.99	0.82-1.21
Not obese	1.00	
Obese	1.30	1.11-1.54
Low acculturation	1.00	
High acculturation	1.07	0.89-1.30
Never drinker	1.00	
Former drinker	1.48	1.12-1.95
Current drinker	1.21	0.97-1.51
Never smoker	1.00	
Former smoker	1.03	0.82-1.29
Current smoker	1.24	0.95-1.63
Do not use texting	1.00	
Use texting	1.15	0.95-1.39

[a]OR: odds ratio.

[a]PA: physical activity.

[a]HS: high school.

Table 5. Multivariate adjusted odds ratios (95% CI) of mobile phone nonusers for meeting physical activity recommendations and sitting 3 or more hours/day.

Variable	OR[a]	95% CI
Meeting PA[b] recommendations		
Not married	1.00	
Married	2.01	1.09-3.68
Sitting 3 or more hours/day		
Female	1.00	
Male	1.73	0.96-3.11
Mexico-born	1.00	
US-born	2.56	1.05-6.21
Low acculturation	1.00	
High acculturation	1.57	0.83-2.95
Never smoker	1.00	
Former smoker	1.48	0.73-3.01
Current smoker	1.26	0.53-2.97

[a]OR: odds ratio.

[b]PA: physical activity.

Discussion

Our results highlight characteristics associated with mobile phone use and behavior in Mexican American adults, including age, birthplace, education, acculturation, and sex, and our study also reveals PA and sitting time differences between users and nonusers of mobile phones. In particular, mobile phone users were more obese, younger, from the United States, more educated, and reported more sitting time and PA than mobile phone nonusers. Meeting PA recommendations was associated with being male, using text messages, and higher acculturation. Although several studies have used mobile devices for increasing PA [4,5,9,10,23], few have examined the associations between mobile phones and behavior, and this study is among the first to quantify these associations among PA, sitting time, and various sociodemographic factors among users and nonusers of mobile phones in Mexican Americans.

In support of our findings, one national study of Hispanic people also reported that younger age and higher education were associated with mobile phone use [24], and the percentage of mobile phone users in our study was similar to that in other publications [7,11]. Lepp et al [8] showed that high frequency mobile phone use in college students was associated with less PA and more sedentary behavior. Although overall frequency of mobile phone use was not assessed in this study, mobile phone users among our participants were more likely to meet PA recommendations than nonusers and were less likely to sit 3 or more hours per day. Our findings are consistent with a study of Latina adolescents showing that mobile phone users report greater PA levels [25]. Additionally, one pilot study found that mobile phone use was associated with a decrease in the average number of daily minutes spent sitting in front of the television [26]. These results in combination indicate that mobile phones should be further studied to examine their potential for promoting PA and reducing sitting time in Hispanic populations.

Interestingly, factors associated with mobile phone use closely resemble those associated with acculturation. In particular, mobile phone users were more likely than nonusers to be obese, be more educated and have a higher acculturation score, and be born in the United States and live there longer, supporting results of previous research [24,25]. Other studies have shown that acculturation is positively associated with PA [16,26,27] and efforts to promote activity levels could be directed toward individuals with low acculturation scores. It is possible that acculturation might explain PA levels and mobile phone use in these participants. Further exploration is necessary to fully explain these differences.

Younger Hispanic adults are more likely to own a mobile device than older adults [7,24] and are also more likely to be physically active as found in this study, which may help explain differences among users and nonusers for meeting PA recommendations. More research is needed to determine why mobile phone users report less sitting time than nonusers.

In agreement with previous studies [16,17,28], males were more likely than females to meet PA recommendations and were also more likely to sit 3 or more hours per day. Our findings suggest that less than 40% of Mexican Americans meet US PA recommendations, which indicates this could be a potential target for a mobile phone intervention to improve health. Healthy People 2020 set a goal of 47.9% of US adults engaging in enough PA to meet recommendations [29], and research is needed to determine if mobile phones can be used to help reach this goal.

Mobile phone users who used text messaging were more likely to meet PA recommendations. It is not known how text messaging may influence domain-specific PA, such as leisure

time or work activity; however, one pilot study in Latino adults found that an intervention providing daily text messages for 6 weeks resulted in an average increase of 146 minutes of exercise per week [30]. It is also possible that the mobile phone users possess smartphones that enable the users to increase their awareness and support for PA behavior through apps and Internet capabilities. One limitation of this study is that information on smartphone use (including mobile phone apps) and ownership was not collected, despite the increasing popularity and prevalence of this technology. Considering the wide array of PA apps available on smartphones and the fact that 64% of Hispanic people now own a smartphone [31,32], future research should examine the potential of these apps for helping Mexican American adults meet US PA recommendations.

Other limitations of this study include the cross-sectional and self-report nature of the data collected, which limits the ability to draw causal inferences and may subject the data to objectivity bias. Additionally, although the sitting time variable has acceptable reliability in adults, recent reports suggest that both men and women underreport their sitting time [33], which may have influenced results here. Furthermore, a single item assessing sitting time may not fully capture the entire spectrum in which an adult sits. Lastly, large portions of the data on media use of the mobile phones (eg, playing music or accessing the Internet) were missing and thus were not used in analyses. The media use data might be helpful for determining ways to promote PA using mobile phones, and future research should consider the best method for collecting this type of data.

In conclusion, this study identified associations between mobile phone use, text messaging, and PA in Mexican American adults, as well as behavioral differences between mobile phone users and nonusers. Mobile phone interventions have shown the ability to increase activity levels [4,5,9,10,34] and could certainly be tailored to promote PA in Mexican American mobile phone users. Future studies should examine the effects of text messaging for promoting domain-specific PA and determine ways to promote PA in those who do not use mobile phones because they are less active than mobile phone users.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
IPAQ: International Physical Activity Questionnaire
OR: odds ratio
PA: physical activity
US: United States

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Original Paper

Parent Use and Efficacy of a Self-Administered, Tablet-Based Parent Training Intervention: A Randomized Controlled Trial

Susan M Breitenstein[1*], RN, PhD; Louis Fogg[1], PhD; Edith V Ocampo[1], MS; Diana I Acosta[1], BA; Deborah Gross[2*], FAAN, RN, DNSc

[1]Rush University, College of Nursing, Chicago, IL, United States

[2]Johns Hopkins University, School of Nursing, Baltimore, MD, United States

[*]these authors contributed equally

Corresponding Author:
Susan M Breitenstein, RN, PhD
Rush University
College of Nursing
600 S. Paulina Street
Chicago, IL,
United States
Phone: 1 312 942 6259
Fax: 1 312 942 6226
Email: susan_m_breitenstein@rush.edu

Abstract

Background: Parent training programs are traditionally delivered in face-to-face formats and require trained facilitators and weekly parent attendance. Implementing face-to-face sessions is challenging in busy primary care settings and many barriers exist for parents to attend these sessions. Tablet-based delivery of parent training offers an alternative to face-to-face delivery to make parent training programs easier to deliver in primary care settings and more convenient and accessible to parents. We adapted the group-based Chicago Parent Program (CPP) to be delivered as a self-administered, tablet-based program called the *ez*PARENT program.

Objective: The purpose of this study was to (1) assess the feasibility of the *ez*PARENT program by examining parent satisfaction with the program and the percent of modules completed, (2) test the efficacy of the *ez*PARENT program by examining the effects compared with a control condition for improving parenting and child behavior in a sample of low-income ethnic minority parents of young children recruited from a primary care setting, and (3) compare program completion and efficacy with prior studies of the group-based CPP.

Methods: The study used a two-group randomized controlled trial (RCT) design with repeated measures follow up. Subjects (n=79) were randomly assigned to an intervention or attention control condition. Data collection was at baseline and 12 and 24 weeks post baseline. Parents were recruited from a large, urban, primary care pediatric clinic. *ez*PARENT module completion was calculated as the percentage of the six modules completed by the intervention group parents. Attendance in the group-based CPP was calculated as the percentage of attendance at sessions 1 through 10. Satisfaction data were summarized using item frequencies. Parent and child data were analyzed using a repeated measures analysis of variance (RM-ANOVA) with simple contrasts to determine if there were significant intervention effects on the outcome measures. Effect sizes for between group comparisons were calculated for all outcome variables and compared with CPP group based archival data.

Results: *ez*PARENT module completion rate was 85.4% (34.2/40; 95% confidence interval [CI] = 78.4%-93.7%) and was significantly greater (P<.05) than face-to-face CPP group attendance (135.2/267, 50.6%) attendance of sessions; 95% CI = 46.8%-55.6%). *ez*PARENT participants reported the program as very helpful (35/40, 88.0%) and they would highly recommend the program (33/40, 82.1%) to another parent. *ez*PARENT participants showed greater improvements in parenting warmth ($F_{1,77}$ = 4.82, P<.05) from time 1 to 3. No other significant differences were found. Cohen's d effect sizes for intervention group improvements in parenting warmth, use of corporal punishment, follow through, parenting stress, and intensity of child behavior problems were comparable or greater than those of the group-based CPP.

Conclusions: Data from this study indicate the feasibility and acceptability of the *ez*PARENT program in a low-income, ethnic minority population of parents and comparable effect sizes with face-to-face delivery for parents.

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KEYWORDS

Internet, intervention, mobile app, mobile health, parenting, prevention

Introduction

Background

Behavioral, social, and emotional difficulties that begin early in life have long-term learning, academic, and relational consequences [1-3]. Chronic pediatric mental health problems are among the top five disabilities affecting children in the United States and now more prevalent than childhood physical disabilities [4,5]. Importantly, many of these social, emotional, and behavioral problems begin in the preschool years [2].

Prevention and intervention in the preschool years is critical before the behavior problems become fixed and disabling [6,7]. Pediatric primary care clinicians are often the first professionals that families solicit regarding parenting concerns or behavioral problems in their children [8,9]. Although a significant need exists in pediatric primary care for programs that teach effective parenting and prevent behavior problems these programs are not readily accessible to clinicians and parents. The purpose of this study was to examine the use and efficacy of a tablet-based parent training program (the *ez*PARENT program) in a sample of parents recruited from a pediatric primary care setting.

Parent training (PT) - a set of systematic programs for teaching parents child management skills - is widely used to promote positive parenting and reduce behavioral risk in young children [10,11]. Early prevention efforts focused on PT are important because parent behavior is a modifiable risk factor for early child behavior problems and improving positive and skilled parenting is a powerful predictor of positive child outcomes [10,12,13]. Though PT programs have been shown to be effective, there are two important limitations to these programs commonly delivered in face-to-face group or individual settings. These limitations include low parent participation rates, particularly among low-income parents, and implementation challenges in existing primary health care systems.

Parent attendance rates for those who enroll in PT typically range 35% to 50% of sessions and up to one-third who sign up attend no sessions [14,15]. Primary logistic barriers to enrollment and attendance in group-based PT include lack of time, childcare, schedule conflicts, and competing demands [14,16]. For low-income families, these barriers may be magnified by concerns with transportation, childcare, and neighborhood safety; as well as demands from work, family and friends, high stress, and poor health.

In addition to parent participant barriers, there are practice barriers. Although pediatric primary care is an ideal venue for programs for improving parenting and preventing behavior problems, there are limited treatment and prevention options that fit into the primary care setting [17]. Indeed, PT programs are traditionally delivered in face-to-face formats (either individually or in group-based settings) and require trained facilitators and weekly parent attendance. Implementing multiple face-to-face sessions of PT is challenging in a busy primary care setting. For instance, a typical well-child visit lasts 8 to 18 minutes during which time clinicians are expected to complete activities including a physical exam, assessment of developmental milestones met, assessment of the child's nutritional status, and deliver any treatments and immunizations. Providing in depth parenting guidance to families struggling with children's emotional or behavioral problems may be unrealistic [18,19]. Further, clinicians' time for pediatric visits related to behavioral problems is reimbursed at a significantly lower rate than general medical visits [19]. The use of Internet-based methods to deliver PT is a feasible and potentially cost-effective approach to address the challenges of delivering PT in primary care settings. Internet delivery addresses issues related to parent participation by increasing accessibility, availability, and parent-controlled access.

The *ez*PARENT Program

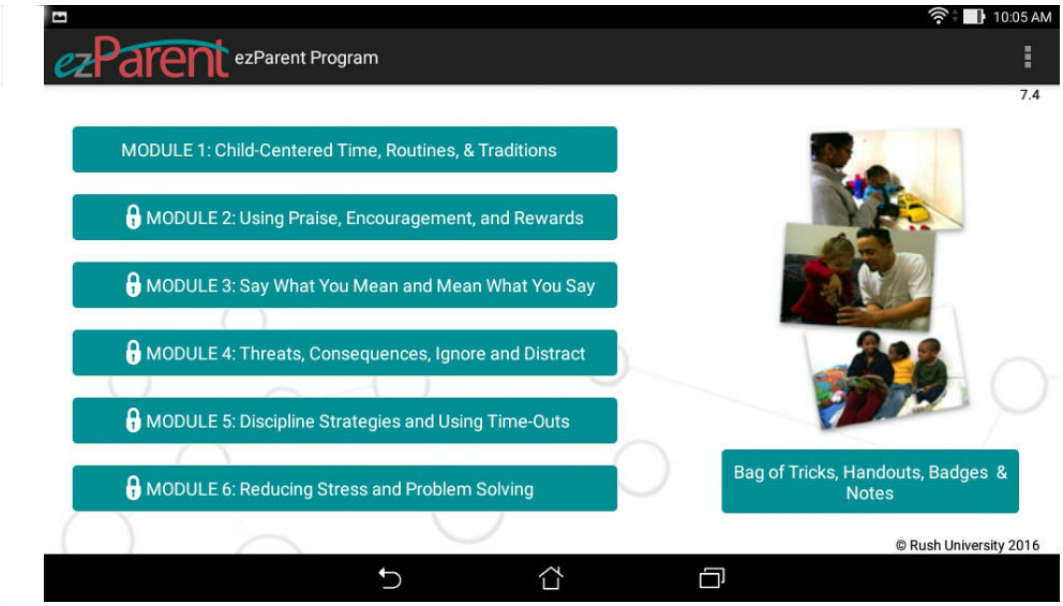
The *ez*PARENT program is a delivery adaptation of the evidence-based, group delivered Chicago Parent Program (CPP). The program is a prevention intervention designed to promote parenting competence and prevent child behavior problems in children 2- to 5-years old [20,21]. Like the group-based program, the six modules of the *ez*PARENT program teach parents evidence-based strategies for encouraging good behavior and decreasing misbehavior in children. See Figure 1 for a list of module content. The *ez*PARENT Program was originally named the *electronic*CPP and changed to the *ez*PARENT Program in 2016. For a full description of the development of the program see Breitenstein et al [20].

The *ez*PARENT program is a self-administered program that is downloaded onto an Android tablet computer as an app. It is one of the first adaptations of an evidence-based group delivered program to incorporate tablet-based technology. The program is set up so that users move sequentially through the modules (ie, parents must complete the first module prior to the second module being unlocked). Once a module is unlocked, parents can access the module and return to any portion of that module at a later time. We estimate that initial completion of one module would take approximately 1 hour [20].

Like other PT programs, rather than focusing primarily on education or increasing knowledge, the *ez*PARENT program assists parents in acquiring a range of evidence-based parenting skills [13,20]. There are several unique aspects of the *ez*PARENT program developed to promote parent engagement and support learning. These are (1) video vignettes of parents interacting with their children, which support vicarious learning and present examples of the various parenting strategies, (2) knowledge questions, which assess parent understanding of the module content and provide added information when needed, (3) interactive "game" activities, which are intended to be fun and keep parents stimulated and engaged, and (4) module practice assignments, which provide opportunities for parents to practice what they are learning with their children [20].

Consistent with the group-based CPP, the *ez*PARENT program is designed to be culturally and contextually relevant for low-income, ethnically diverse parents of young children [21]. During the development of the tablet program, we worked with low income and ethnic minority parents to assure the content was relevant and that the app was easy to use, attractive, and interesting [20]. The use of mobile technology allowed us to design the program to be interactive and accessible, a particularly salient feature for African American and Hispanic parents who are among the most active users of the mobile Internet [22,23]. Therefore, parent training via an app on mobile devices may be an ideal method to increase the reach and accessibility of parent training programs, particularly among low-income African-American and Hispanic families.

Figure 1. ezPARENT program home page and module topics.



Study Purpose and Hypothesis

The purpose of this study was to establish the feasibility and efficacy of the *ez*PARENT program. To examine feasibility, we examined parent satisfaction with the program and the percent of modules completed relative to percent of face to face sessions attended in prior studies of the group-based CPP. To test efficacy, we examined the effect of the *ez*PARENT program against an attention control condition for improving parenting and child behavior in a sample of low-income ethnic minority parents of young children recruited from a primary care setting. We hypothesized that the percent of *ez*PARENT modules completed would be comparable to or greater than the percent of group-based CPP session completed; compared with an attention control group, parents in the *ez*PARENT intervention group would report using more positive discipline strategies, greater parenting self-efficacy, and decreased parenting stress and child behavior problems; and effect sizes for improvement in parent and child behaviors would be comparable to or greater than the group-based CPP.

Methods

Trial Design

The study used a two-group randomized control trial (RCT) design with repeated measures follow-up. Subjects were randomly assigned to either the intervention (*ez*PARENT group) or attention control condition (health promotion group). Data collection in both conditions was at baseline and at 12 and 24 weeks post baseline. This study was reviewed and approved by the University's institutional review board.

Parents in the *ez*PARENT group received the six module *ez*PARENT program to be completed over a 12-week period (allowing approximately 2 weeks per module). During the same time period, parents in the health promotion control group received information on various topics (ie, nutrition, exercise, finance, safety, medical information, and entertainment) via a website that included links and portable document format handouts for each topic. These materials were the same health promotion handouts and websites distributed at the primary care pediatric recruitment site. The health promotion condition was designed to control for attention related to technology use over the same period of time.

Sample

Parents were eligible to participate in the study if they were the parent or legal guardian of a child between the ages of 2 to 5 years, the child was receiving or eligible to receive Medicaid insurance (eg, All Kids Assist or Share in Illinois), and the child received medical care at the pediatric primary care recruiting site. Only one parent per family participated in the study. If a parent had more than one child between the ages of 2 and 5 years, the parent selected one child to report on their behavior over the length of the study. Currently, the *ez*PARENT program is only available in English; therefore, parents who were unable to speak and read English were excluded.

Parents were recruited between October 2013 and June 2014 from a large, urban, primary care pediatric clinic located on the near west side of Chicago. According to the clinic, most of the families they serve are African American (50%) or Latino (30%) and over 65% of families have low incomes or receive Medicaid. We advertised broadly at the primary care site using project

flyers that contained information about the purpose of the study, inclusion criteria, expectations for participation, and contact information for parents to directly contact the study staff. An interest form was included in the flyer; parents completed the form indicating their willingness to be contacted by the study staff. If a parent was eligible and interested in participating, then a 2-hour meeting was scheduled in our research offices to complete the participant consent, baseline data collection, and randomization to condition.

Figure 2 depicts the participant flow in the trial. Two hundred eighty-seven parents were assessed for eligibility. Of the 118 parents eligible for the study, 70.3% (83/118) of parents consented to participate, completed baseline assessments, and were randomized to either the *ez*PARENT or health promotion control condition. Of the 83 parents randomized, 79 parents completed follow-up assessments (95.2% retention rate).

The sample was predominantly comprised of single, ethnic minority (African-American or Hispanic) mothers of young children earning annual incomes of less than $20,000 (see Table 1). There were no significant demographic differences between the intervention and control groups.

Variables and Measures

Module Completion and Satisfaction

Parents earn a "module badge" at the end of each module and after they review the practice assignment. After completion of the module, parents are alerted with a pop-up in the program congratulating them on earning the module badge. Parents can view their earned badges in the "my badges" section of the program. The *ez*PARENT digital platform provides time stamps of when parents earn the module badge. Intervention dose was defined by parent receipt of the module badge. For this analysis, we included badges that were earned prior to the 12 week post baseline data collection appointment corresponding with the intervention completion period (eg, 6 modules × 2 weeks per module).

Satisfaction was measured using an end of program survey administered 6 months after baseline. Parents rated how helpful they found the *ez*PARENT program (very helpful, a little helpful, or not at all helpful), their overall satisfaction with the program (very dissatisfied, dissatisfied, satisfied, or very satisfied), and whether they would recommend the *ez*PARENT program to other parents (not recommend, recommend, or highly recommend). Parents in the control group rated their perception of helpfulness (very helpful, a little helpful, or not at all helpful) of the information provided in the health promotion website (eg, nutrition, exercise, finances, safety, medical, and entertainment) and whether they would recommend the website to other parents (not recommend, recommend, or highly recommend).

Figure 2. CONSORT flow diagram.

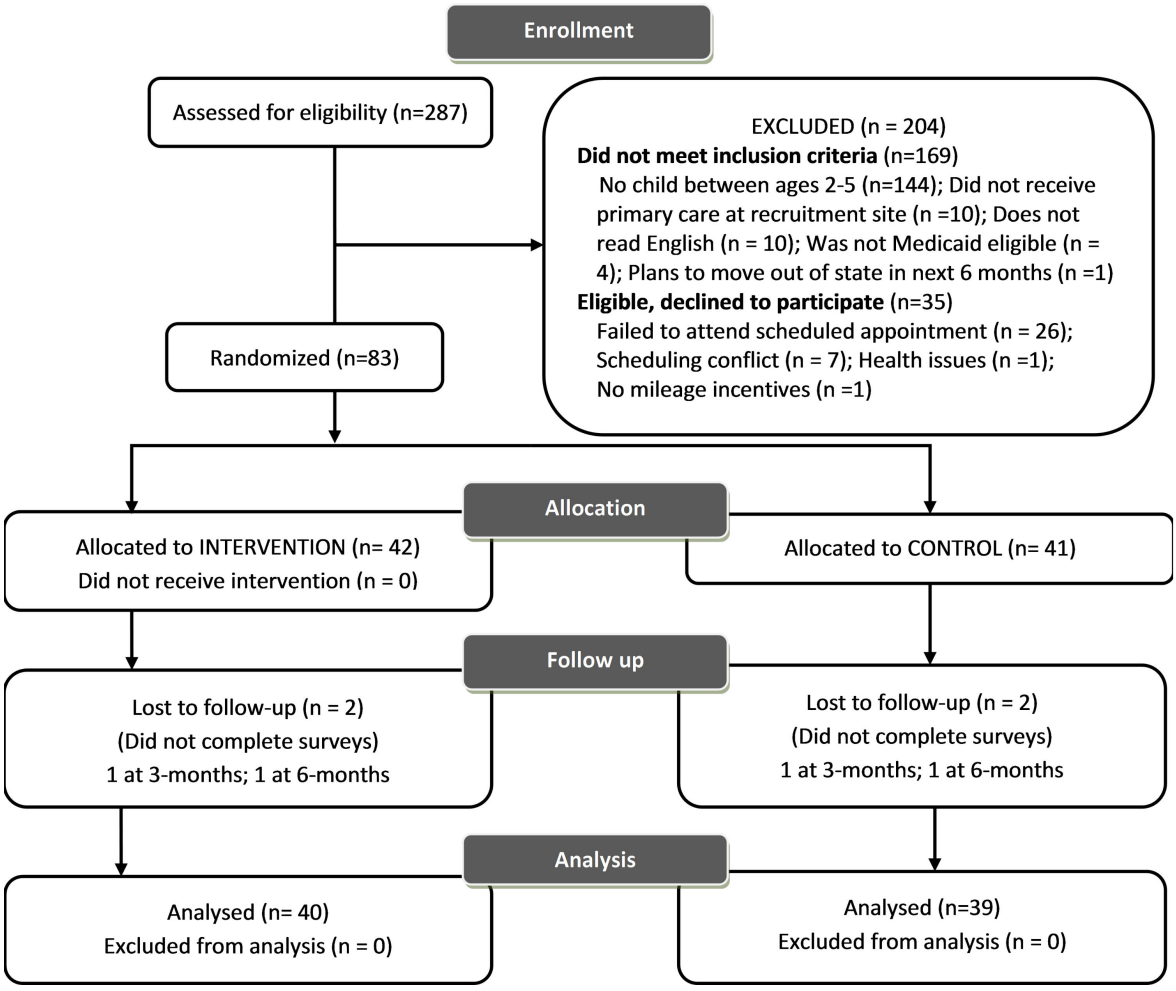


Table 1. Study participant demographics (N=79; frequency [%]).

Demographic Variable	Full Sample N=79 n (%)	Control n=39 n (%)	Intervention n=40 n (%)
Child Age			
2-years old	18 (22.8%)	10 (25.6%)	8 (20.0%)
3-years old	17 (21.5%)	10 (25.6%)	7 (17.5%)
4-years old	29 (36.7%)	14 (35.9%)	15 (37.5%)
5-years old	15 (19.0%)	5 (12.8%)	10 (25.0%)
Child gender			
Female	45 (57.0%)	22 (56.4%)	23 (57.5%)
Male	34 (43.0%)	17 (43.6%)	17 (42.5%)
Relationship to child			
Mother	75 (94.9%)	37 (94.9%)	38 (95.0%)
Foster Mother	1 (1.3%)	1 (2.6%)	--
Grandmother	3 (3.8%)	1 (2.6%)	2 (5.0%)
Parent age			
age 18-29	27 (34.2%)	15 (38.5%)	12 (30.0%)
age 30-49	50 (63.3%)	23 (59.0%)	27 (67.5%)
age 50+	2 (2.5%)	1 (2.6%)	1 (2.5%)
Parent race/ethnicity			
African American	51 (64.6%)	28 (71.8%)	23 (57.5%)
Hispanic	24 (30.4%)	10 (25.6%)	14 (35.0%)
White/other[a]	4 (5.1%)	1 (2.6%)	3 (7.5%)
Parent education			
Less than high school	7 (8.9%)	2 (5.1%)	5 (12.5%)
High school/GED	10 (12.7%)	6 (15.4%)	4 (10.0%)
Some college/AD	49 (62.0%)	23 (59.0%)	26 (65.0%)
College/Graduate school	13 (16.5%)	8 (20.5%)	5 (12.5%)
Parent employment status			
Working	36 (46.2%)	21 (55.3%)	15 (37.5%)
Not Working	42 (53.8%)	17 (44.7%)	25 (62.5%)
Annual income			
< $20,000/yr	52 (65.8%)	24 (61.5%)	28 (70.0%)
$20,000-$40,000/yr	22 (27.8%)	11 (28.2%)	11 (27.5%)
> $40,000/yr	5 (6.3%)	4 (10.3%)	1 (2.5%)
Marital status			
Married or domestic partnership	22 (27.8%)	12 (30.8%)	10 (25.0%)
Never married	48 (60.8%)	21 (53.8%)	27 (67.5%)
Divorced or separated	9 (11.4%)	6 (15.4%)	3 (7.5%)

[a]One parent identified as Cherokee Indian, German, Irish, and Italian.

Parent Outcomes

Parenting self-efficacy, behavior, and stress were assessed using self-report measures. The 38-item Toddler Care Questionnaire (TCQ) was used to measure parenting self-efficacy [24]. The TCQ measures parent self-efficacy in managing situations and tasks that are specific to raising young children. TCQ scale scores range from 38 (not at all confident) to 190 (very confident). Reliability (Cronbach's alpha) for the TCQ for this sample was 0.94.

Parent discipline strategies were measured using the 40-item Parenting Questionnaire (PQ) [25,26]. The PQ includes three discipline scales measuring parental warmth (Warmth), extent to which they follow through on discipline (Follow Through), and use of corporal punishment (Corporal Punishment). Parents rate each item on a scale of 1 (almost never) to 5 (very often). Reliability (Cronbach's alpha) for the PQ scales were 0.88 (Warmth), 0.81 (Follow Through), and 0.66 (Corporal Punishment).

The 36-item Parenting Stress Index-Short Form (PSI-SF) was used to measure parenting stress. The PSI-SF is derived from the validated 101-item PSI and mirrors the strong validity of the PSI [27]. Parents respond to items on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree) resulting in a total stress score. Higher scores on the PSI-SF indicate higher parenting stress. The PSI-SF also includes a published cut-off score for clinically significant stress based on scores above the 85th percentile [28]. Reliability (Cronbach's alpha) for the PSI-SF for this sample was 0.92.

Child Behavior Problems

Parents reported child behavior problems using the 36-item Eyberg Child Behavior Inventory (ECBI) [29]. The ECBI is for parents of children ages 2- to 16-years old and assesses problem behavior on two scales, the Intensity Scale and the Problem Scale. The Intensity Scale assesses the frequency of 36 problem behaviors on a 7-point scale ranging from 1 (the behavior never happens) to 7 (the behavior is always happening). The Problem Scale assesses parent perception of each of the behaviors as being problematic for him or her as a parent (yes or no). The ECBI includes cut off scores for each scale indicative of clinical significant child behavior problems based on scores that are 1.5 standard deviations (SD) above the mean (the 93rd percentile) [29]. Reliability (Cronbach's alpha) for the ECBI for this sample was 0.92 (Intensity Scale) and 0.93 (Problem Scale).

Group-Based CPP Archival Data

The data obtained in this study were compared with group-based CPP archival data collected on a racially, ethnically, and socioeconomically comparable sample of 267 parents that received the intervention as part of a RCT [15]. There were no significant differences between the group-based intervention group (n=267) and the *ez*PARENT intervention group (n=40) for income or race. Data were compared on intervention dose (ie, percent of *ez*PARENT module completion versus percent of face-to-face parent sessions attended) and effect size changes in parenting self-efficacy (TCQ), parent discipline strategies (PQ), and child behavior (ECBI). Comparison of the *ez*PARENT and group-based CPP effect size estimates is important in establishing the comparability of the magnitude of treatment effects of the intervention using different delivery methods. The group-based CPP includes 12, 2-hour group sessions facilitated by two trained leaders [21]. The six modules of the *ez*PARENT program parallel the content of the first 10 sessions of the group-based CPP (see Textboxes 1 and 2) [20]. The 11th and 12th group sessions do not include new content and are used to help parents synthesize the knowledge and skills acquired from the prior sessions, these sessions correspond with the review materials included in the *ez*PARENT Program.

Textbox 1. ezParent program.

Module 1: child-centered time, routines and traditions
Module 2: using praise, encouragement, and rewards
Module 3**:** say what you mean and mean what you say
Module 4: threats, consequences, ignore and distract
Module 5: discipline strategies and using time-outs
Module 6: reducing stress and problem solving
Module Reviews: summary materials, handouts, and ability to return to any module content

Textbox 2. CPP-group based topics.

Week 1: child-centered time
Week 2: family routines and traditions
Week 3: using praise and encouragement
Week 4: using rewards for challenging behaviors
Week 5: say what you mean and mean what you say
Week 6: threats and consequences
Week 7: using ignore and distract
Week 8: using time-outs
Week 9: reducing your stress
Week 10: problem solving
Week 11: putting it all together (session 1-10 review)
Week 12: booster session (1-2 months later)

Procedures

At their first study appointment, parents were enrolled in the study by completing the informed consent process and responding to all demographic and survey instruments. Consents and survey data were collected on an Internet-based data collection app developed for this study. The goal of using Internet-based data collection was to increase the efficiency and ease of data collection and entry. Prior to recruitment, study staff tested the data collection app for ease of use and accuracy of data collection. Once established, the data collection app was launched. Total time for completion of the surveys at baseline was 35 to 40 minutes. Randomization to group assignment was made using stratified random sampling based on time sequential cohorts. The randomization table was built into the data collection app and group assignment was made after all baseline data were acquired. Parents were assured that the study assignment was random and had no connection with their responses to the survey questions. After study assignment was revealed, all parents in the control and intervention groups were given Android tablets to use for the duration of the study.

Intervention Fidelity

Several strategies were implemented to ensure intervention fidelity (eg, strategies to monitor and enhance the reliability and validity of the intervention) [30]. After study assignment was revealed, the study staff provided a structured training (using written and verbal information) to all participants on how to use the tablet. Additional training was then provided specific to assigned condition. Following training, parents were prompted to verbalize their understanding and conducted return demonstrations to assess ability to use the tablet and the health promotion website (control) or *ez*PARENT app (intervention).

Parents in the *ez*PARENT condition received automated text message reminders to complete the *ez*PARENT program if they had not completed the module content. Automated text messages also included positive encouragement regarding completion of the program and of practice assignments. These messages were consistent across all intervention parents.

Analytic Approach

Parent participants were included in the analysis nondependent on their adherence or nonadherence to the *ez*PARENT program. Parents (n=4) who were lost to follow up after enrollment were not included because we were unable to collect any follow up data for outcome analysis (see Figure 2). Parent completion of the *ez*PARENT modules was calculated as the percentage of the six modules completed by each of the intervention group parents (n=40). For comparison to the group-based CPP, intervention attendance was calculated as the percentage of sessions 1 through 10 of the CPP group attended by intervention group parents (n=267). This analysis is based on content completion not on the amount of time spent in either the group-based or tablet-based program. Content across the *ez*PARENT modules and the CPP group sessions is comparable (see Textboxes 1 and 2). The *ez*PARENT and group based rates of participation were compared using 95% confidence intervals (CI). Satisfaction data were summarized using item frequencies.

Chi square tests were used to compare baseline data between parents in the *ez*PARENT and health promotion control group and determine if there were significant differences. Parent and child data were analyzed using a repeated measures analysis of variance (RM-ANOVA) with simple contrasts to determine if there were significant intervention effects on the outcome measures from baseline to 12 weeks post baseline (T1 to T2) and from baseline to 24 weeks post intervention (T1 to T3).

Effect sizes for between group comparisons were calculated for all outcome variables using Cohen's d [31]. For comparison to the group-based CPP, we calculated effect sizes from data published by Breitenstein and colleagues [15] (effect size comparisons for the PSI-SF are not included as this measure was not part of the group-based evaluation). Effect sizes were calculated T1 to T2 and for T1 to T3 using the following equation:

$$(x_{t1} - x_{t2}) - (x_{c2} - x_{c1}) / SD_{pooled}$$

where x_{t2} = treatment group mean at time 2; x_{t1} = treatment group mean at time 1; x_{c2} = control group mean at time 2; x_{c1}

= control group mean at time 1; and SD_{pooled} = the pooled SDs of all reported groups (eg, treatment and control) [31].

Results

*ez*PARENT Module Completion

Table 2 presents the percent of the sample completing each module (ie, earned a module badge) during the first 3 months of the study and the percent of parents in the archival comparison sample attending the face to face CPP group-based sessions. All parents in the *ez*PARENT sample earned the module 1 completion badge. Across all six modules, the average *ez*PARENT module completion by parent was 85.4% (34/40) of modules (95% CI = 74.5%-96.4%). In contrast, average parent attendance for the face-to-face CPP groups was 50.6% (135/267) of sessions (95% CI = 44.6%-56.6%), and 24% (64/267) of the archival CPP sample failed to attend any sessions [15]. The *ez*PARENT dose rate was higher than the upper CI for the group CPP dose, suggesting that parent participation rates of the *ez*PARENT and group based CPP were significantly different (P<.05).

Table 2. *ez*PARENT module (n=40) and CPP group-base (n=267) Dose.

*ez*PARENT module	Corresponding CPP group session(s)	*ez*PARENT module completion n (%)	CPP group attendance n (%)
Module 1	Sessions 1-2	40 (100%)	157 (58.8%)
Module 2	Sessions 3-4	39 (97.5%)	143 (53.6%)
Module 3	Session 5	38 (95.0%)	134 (50.2%)
Module 4	Sessions 6-7	33 (82.5%)	133 (49.6%)
Module 5	Session 8	29 (72.5%)	120 (44.9%)
Module 6	Sessions 9-10	26 (65.0%)	124 (46.4%)

Satisfaction

Of the parents in the *ez*PARENT group, 87.5% (35/40) reported the *ez*PARENT program being very helpful and 12.5% (5/40) a little helpful. In the control group parent reports of helpfulness of the topics on the health promotion website (control group) ranged from 46.2% (18/39) to 74.4% (29/39) very helpful; 20.5% (8/39) to 28.2% (11/39) a little helpful; and 2.6% (1/39) to 5.1% (2/39) not at all helpful. The nutrition topic in the website was the highest ranked as very helpful. Of parents in the *ez*PARENT condition, 42.5% (17/40) reported that it was a little bit hard to regularly use the *ez*PARENT program, 2.5% (1/40) very hard, and 52.5% (21/40) not at all hard. Satisfaction with the *ez*PARENT program was high, with 80.0% (32/40) of parents reporting they were very satisfied and 20.0% (8/40) reporting they were satisfied with the program.

Parents in the *ez*PARENT group were more likely to recommend the *ez*PARENT Program to other parents than parents recommending the health promotion site (Kendall's *Tau-b* = 0.25; P<0.05). Overall, 82.5% (33/40) of the *ez*PARENT group reported they would highly recommend, 15.0% (6/40) would recommend, and 2.5% (1/40) didn't know if they would recommend the program to another parent. In contrast, 59.0% (23/39) of parents in the health promotion control group reported they would highly recommend, 35.9% (14/39) would recommend, 2.6% (1/39) would not recommend, and 2.6% (1/39) didn't know if they would recommend the website to another parent.

Parent and Child Outcomes

Table 3 presents means and SDs for each variable by condition at each data collection time point. At baseline, there were no significant differences between the *ez*PARENT and health promotion control groups for parent behavior (PQ), self-efficacy (TCQ), and stress (PSI-SF), or child behavior (ECBI). At baseline, 6.3% (5/79) of the sample scored above the PSI cut off score (>109) [28]; 25.3% (20/79) scored above the ECBI problem scale cut off score (>14); and 19% (15/79) of the sample scored above the ECBI intensity scale cut-off score (>130) [29].

From T1 to T3, there was a significant difference between conditions for parenting warmth on the PQ ($F_{1,77}$ = 4.82, P<.05). There were no significant differences between the intervention and control conditions on parents' reports of their follow through on discipline, use of corporal punishment, parenting stress, parenting self-efficacy, or child behavior problems.

In Table 4, we present effect size estimates for the *ez*PARENT program and comparison effect sizes for the group-based CPP [15]. A Cohen's d of .2 is considered a small effect, .5 a medium effect, and .8 or larger a large effect [31]. Effect sizes from T1 to T3 were in the small range for parent warmth (PQ), parent corporal punishment (PQ), follow through (PQ), parenting stress (PSI-SF), and child behavior problems based on the ECBI intensity scale. With the exception of parenting self-efficacy (TCQ) and corporal punishment (PQ), *ez*PARENT effect sizes were comparable or greater than those of the group-based CPP.

Table 3. Mean and standard deviation of outcome variables for intervention (n=40) and control (n=39) groups.

Variable	Assessment Time Point		
	Time 1 (T1)[a] M (SD)	Time 2 (T2)[b] M (SD)	Time 3 (T3)[c] M (SD)
Parent warmth (PQ[d])			
Intervention	94.23 (7.96)	95.15 (7.68)	95.73 (7.34)
Control	95.08 (10.04)	95.39 (7.43)	93.67 (11.71)
Parent corporal punishment (PQ)			
Intervention	6.00 (2.00)	5.85 (2.4)	5.58 (2.16)
Control	6.36 (2.58)	5.92 (2.22)	6.26 (2.45)
Parent follow through (PQ)			
Intervention	20.18 (5.32)	21.48 (4.65)	21.65 (5.13)
Control	18.85 (4.94)	19.00 (5.27)	19.36 (5.67)
Parenting self-efficacy (TCQ[e])			
Intervention	165.50 (17.12)	167.70 (14.43)	169.13 (14.81)
Control	163.44 (21.69)	167.31 (23.37)	164.51 (23.94)
Parenting stress (PSI-SF[f])			
Intervention	75.03 (20.30)	70.24 (19.32)	67.90 (17.34)
Control	75.89 (19.00)	70.95 (20.98)	72.46 (20.61)
Child behavior problems (ECBI[g])			
Intervention	7.41 (6.59)	5.78 (6.06)	5.50 (5.74)
Control	10.08 (8.79)	7.18 (7.59)	8.11 (8.85)
Child behavior intensity (ECBI)			
Intervention	103.55 (28.94)	96.68 (29.96)	94.88 (26.89)
Control	104.79 (29.59)	98.04 (27.92)	101.23 (30.74)

[a]Baseline.

[b]3 months post baseline.

[c]6 months post baseline.

[d]Abb: Parent Questionnaire.

[e]Abb: Toddler Care Questionnaire.

[f]Abb: Parenting Stress Index-Short Form.

[g]Abb: Eyberg Child Behavior Inventory.

Table 4. Comparison of between group effect size estimates of *ez*PARENT Program (n=40 control; n=39 intervention) and group CPP (n=237 control; n=267 intervention).

Variable	Effect Sizes			
	Time 1-2[a,b]		Time 1-3[a-c]	
	ez P ARENT	Group CPP[a]	*ez* P ARENT	Group CPP[d]
Parent warmth (PQ[e])	0.07	-0.06	0.31	0.10
Parent corporal punishment (PQ[e])	-0.13	0.15	0.14	0.26
Parent follow through (PQ)	0.23	0.17	0.18	0.08
Parenting self-efficacy (TCQ[f])	-0.09	0.21	0.13	0.22
Parenting stress (PSI-SF[g])	-0.01	-- [b]	0.19	-- [i]
Child behavior problems (ECBI[h])	-0.18	-0.06	-0.01	0.05
Child behavior intensity (ECBI)	0.00	0.19	0.18	0.20

[a]Baseline.

[b]12 weeks post baseline.

[c]24 weeks post baseline.

[d]Effect sizes estimated from data in Breitenstein et al [15].

[e]Abb: Parent Questionnaire.

[f]Abb: Toddler Care Questionnaire.

[g]Abb: Parenting Stress Index;

[h]Abb: Eyberg Child Behavior Inventory.

[i]PSI-SF was not reported in Breitenstein et al [15].

Discussion

Principal Findings

In this study we evaluated the feasibility, acceptability, and preliminary efficacy of the tablet-based adaptation of the CPP, the *ez*PARENT program, in a sample of low-income, ethnic minority parents of 2- to 5-year-old children seen in primary care. The CPP is an evidence-based parenting skills program originally designed to be delivered in a face-to-face parent group format [21]. However, like many preventive interventions targeting low-income families that require face-to-face involvement, participation rates have typically been low [14,16]. Moreover, pediatric primary care providers, who serve a large population of families receiving Medicaid, are often unable to devote the time needed to provide parenting skills training and support. These problems diminish the impact and reach of evidence-based parenting programs. Given the challenges of using face-to-face formats for parenting skills training, we were particularly interested in examining the amount of intervention (ie, dose) parents would receive using a self-administered digital format for acquiring parenting skills training compared with a face-to-face group format.

Overall, the results indicate that the *ez*PARENT program is feasible and acceptable in a low-income, ethnic minority population of parents. Compared with a control group of parents using a health promotion website, *ez*PARENT program parents were more likely to report that they would recommend the program to another parent. Compared with a comparable archival sample of parents enrolled in the face to face group-based CPP, parents enrolled in *ez*PARENT received a higher dose of parenting content. Specifically, parents in the *ez*PARENT group completed over 85.0% (34/40) of the modules compared with parents in the face-to-face format who attended on average only 50.6% (135/267) of the parent group sessions. Moreover, all of the *ez*PARENT participants completed at least one module whereas 24.0% (64/267) of parents enrolled in the face-to-face group format, never attended a single session. These findings are consistent with a recent review of digitally delivered parenting interventions reporting that 41.7% to 99.2% of participants completed their digitally delivered parent training interventions [32]. Furthermore, these data demonstrate that a digital format for delivering parenting skills training to a predominantly low-income ethnic minority population of parents is feasible and acceptable, and may greatly extend the reach for helping more parents and young children in primary care.

Although module completion rates in this study were promising, there is more work to be done to understand patterns of parent use of the *ez*PARENT program. A benefit of using technology is the ability to track all aspects of parent usage of the app. Digital tracking data can provide important information regarding parent behavior in interacting with the intervention, specifically, how and when parents use the *ez*PARENT program and what content they access. For example, information regarding the number of visits parents make to components of the program, time stamps of visits to each portion of the program, and the frequency which parents return to completed content. In future work, we will conduct detailed analysis of this usage data. Indeed, research of Internet-delivered interventions is beginning to emerge related to patterns of program use and intervention outcome [33,34]. A fine tune analysis of usage metrics will expand our knowledge related to dose and program effectiveness.

Overall, we found the effects of the *ez*PARENT program on parenting and child behavior problems were in the small range and many were comparable to the effect sizes obtained from archival samples using the CPP in the face-to-face format. Although significant improvements were found for parent use of warmth in their discipline, no improvements were found for parent use of corporal punishment, following through on discipline, parenting stress, and child behavior problems relative to the control group. There are three possible reasons for these results. First, the power calculation for this study was based on estimated effect sizes for intervention dose rather than parent and child outcomes. Much larger sample sizes would be needed to detect significant differences based on small effects, which are typical for prevention studies [35,36]. Therefore, we may not have adequate power to detect differences between the intervention and control parents in this analysis.

Second, although we recruited from a population of families with social risk factors related to parent and child dysfunction (eg, low income), the parents in our study reported low levels of parenting stress and relatively few child behavior problems at baseline. Less than one-quarter of the parents reported child behavior problems exceeding the cut point for clinically significant problems and less than 6.3% (5/79) reported clinically significant levels of parenting stress. Therefore, floor effects in this relatively healthy population may have made it difficult to detect improvements over time. Greater effects may be more detectable in a referred population of parents and young children.

Third, the lack of effects may be due to the limited amount of time allotted for assessing parent and child behavior change. It is possible that more time for parents to absorb the new information, practice the new skills, and observe changes in themselves and their children may yield greater improvements in discipline strategies, parenting self-efficacy, and child behavior.

Study Limitations and Future Directions

Although our findings indicate feasibility and acceptability of the *ez*PARENT program and comparable effect sizes to face-to-face delivery for parents recruited from primary care we recruited from one location from a relatively healthy population. It is possible that parents involved in this study were highly motivated to participate and learn from the intervention. Future studies of the *ez*PARENT program will employ a larger sample size from multiple primary care sites and longer term follow-up to establish the efficacy of the *ez*PARENT program in modifying parent and child behaviors. In addition, to lay the ground work for full scale implementation in primary care sites, implementation, and cost effectiveness of the *ez*PARENT program in primary care will be determined.

Using an archival sample for a comparison group of delivery methods presents methodological limitations because of the lack of experimental control across the two groups. Although not a purpose of the original evaluation of the *ez*PARENT program, we felt it was important to demonstrate an initial comparison of dose and outcome to the group-based CPP. Our analysis suggests they may be comparable but a true test would require a randomized design comparing group-based CPP to *ez*PARENT. Indeed, a RCT structured as an equivalence or noninferiority trial with an adequately powered sample size would allow a head to head comparison of the two formats, directly compare intervention outcomes and dose, and allow us to understand which parents are likely to benefit from each delivery format.

Another potential limitation is the use of parent report to evaluate the intervention. A more robust measure of intervention efficacy could include multi-informant and multimethod data. However, previous findings from RCTs of the group-based CPP have found significant findings across three sources of data: parent self-report, teacher report, and parent-child observation [15,37]. In these studies, the parent self-report findings have consistently agreed with other methods of measuring parent and child outcomes.

It is important to understand how parents use the information and program. In this analysis we assessed one metric of program usage – module completion. Although module completion provides an overall picture of parent dose it does not provide us with specific information related to patterns of use, time spent on the program, and other important data of *ez*PARENT use. In addition, we assessed program use from baseline to the 12-week follow-up even though parents had access to the program throughout the 24-week study period. Therefore, as previously noted, an analysis of usage data is critical in understanding patterns using the *ez*PARENT INTERVENTION AND PARENT'S ONGOING USE OF INFORMATION AFTER THE INITIAL MODULE COMPLETION. THIS INFORMATION WILL HELP UNDERSTAND THE CHANGE MECHANISMS OF THE INTERVENTION. FURTHER, DEMONSTRATING THE PROCESSES AND PATTERNS RELATED TO USING TABLET-BASED BEHAVIOR CHANGE INTERVENTIONS IS IMPORTANT TO THE FIELD OF EHEALTH BEHAVIORAL INTERVENTIONS.

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Conflicts of Interest

Under an agreement between Rush University Medical Center and Dr. Deborah Gross. Dr. Gross is entitled to revenue from sales of the Chicago Parent Program and the adaptation described in this article. This arrangement has been reviewed and approved by the Johns Hopkins University in accordance with its conflict of interest policies.

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Abbreviations

CI: confidence interval
CPP: Chicago Parent Program
ECBI: Eyberg child behavior inventory
PT: parent training
PQ: parenting questionnaire
RCT: randomized controlled trial
RM-ANOVA: repeated measures analysis of variance
PQ: parent questionnaire
PSI-SF: parenting stress index-short form
SD: standard deviation
T1: baseline
T2: 3 months post baseline T3: 6 months post baseline
TCQ: toddler care questionnaire

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Original Paper

Redesign and Validation of Sisom, an Interactive Assessment and Communication Tool for Children With Cancer

Susann Arvidsson[1*], RN, PhD; Britt-Mari Gilljam[1,2*], RN, MSN; Jens Nygren[1*], PhD; Cornelia Maria Ruland[1,3,4*], PhD; Trude Nordby-Bøe[3*], MSN; Petra Svedberg[1*], RN, PhD

[1]School of Health and Welfare, Halmstad University, Halmstad, Sweden

[2]Region Halland, Halmstad, Sweden

[3]The Centre for Shared Decision Making and Collaborative Care Research (CSDM), Oslo University Hospital, Oslo, Norway

[4]University of Oslo, Oslo, Norway

[*]all authors contributed equally

Corresponding Author:
Susann Arvidsson, RN, PhD
School of Health and Welfare
Halmstad University
Box 823
Halmstad, SE-301 18
Sweden
Phone: 46 35 16 71 00
Fax: 46 35 18 61 92
Email: susann.arvidsson@hh.se

Abstract

Background: Children with cancer undergo intensive and long treatment periods that expose them and their families to a number of difficult physical, mental, and social challenges. Empowering children by actively involving them in their care can help them to cope with these challenges. It can, however, be difficult for children to be involved and talk about their illness experiences in a "traditional" conversation with health care professionals, especially for younger children. Sisom (Norwegian acronym "Si det som det er" or "Tell it how it is") is an interactive computer-based assessment and communication tool to give children (aged 6-12 years) with cancer a "voice" in their care. Because of technological advances and widespread use of mobile devices Sisom had to be redesigned to better meet the needs of children of today.

Objective: To redesign Sisom for use on mobile devices and to validate and adapt it for use in a Swedish population of children with cancer.

Methods: A user-experience design was used. Content adaptation included forward-backward translation by Swedish and Norwegian translators. Healthy children (n=5), children with experiences of cancer treatment (n=5) and their parents (n=5), and pediatric nurses (n=2) were then involved in culturally adapting Sisom to the Swedish context. The iterative low- and high-fidelity evaluation was supported by a think aloud method, semistructured interviews, and drawings to capture children's views of Sisom. The redesign and evaluation continued until no further changes or improvements were identified by the participants or the researchers.

Results: Children, parents, and pediatric nurses offered many suggestions for improvements to the original version in terms of content, aesthetics, and usability of Sisom. The most significant change that emerged through user input was a modification that entailed not using problem-focused statements in the assessment items. The parents and pediatric nurses considered the revised assessment items to be general and less diagnosis specific. The evaluation of aesthetics resulted in brighter colors and more positive and exciting details in the animations. The evaluation of usability included improvements of the verbal instructions on how to navigate in Sisom 2, and also that the answers to assessment items in Sisom 2 should be saved to provide the children with the option to pause and to continue answering the remaining assessment items at a later stage.

Conclusions: Overall, this paper describes the process of using user-experience design with children in order to redesign and validate an interactive assessment and communication tool and how the outcomes of this process resulted in a new version, Sisom 2. All participants confirmed the usability and qualities of using the final version. Future research should be directed toward the implementation of Sisom 2 in clinical practice and to evaluate outcomes from individual and organizational levels.

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KEYWORDS

cancer; children; communication; mobile app; participation; validation

Introduction

Children who have life-threatening diseases such as cancer [1] undergo intensive and long treatment periods that expose them and their families to physical, mental, and social challenges. One way for children to cope with the challenges is to be involved in their own care [2]. Children also want to be listened to and wish to be included in discussions about their own care, in information sharing, and to be involved in minor decisions [2-5]. Many health care professionals recognize the need to include children in their own care [2,6,7]. However, children's rights for participating is still unsatisfactorily applied in health care [8] and children's own needs and preferences are often neglected in health care situations [5,9]. It is thus important to increase health care professionals' awareness of the benefits of including children in their own health care [6,10]. New mobile devices have begun to transform the way health care professionals deliver health care and have the potential to increase children's participation in their own care by providing appealing and easy-to-use digital services that can contribute to change communication patterns between children and health care professionals [11].

Children's involvement in their own health care, regardless of disease, is a fundamental right [12]. When health care professionals acknowledge and respect children as actors and promote their opportunities to participate in health care settings together with their family, a child-centered approach is attained. It is important that such an approach contains both the adults' perspective concerning the child's best interest and the child's own perspective concerning respect for what is important to her or him. When health care professionals and parents have a child's perspective, they are attentive, sensitive, and supportive to the child, irrespective of the child's age, gender, and so on [13]. Children have to be treated as individuals, and health care professionals and other adults must take into account that a child's competence and preferences depend on situational circumstances [14]. It can, however, be difficult for children, especially younger ones, to talk about their experiences in a "traditional" conversation with health care professionals and with other adults. In order to overcome this problem, Sisom (Norwegian acronym "Si det som det er" or "Tell it how it is") was developed. Sisom is an interactive computer-based assessment and communication tool for children with cancer [15,16] and heart disease [17] aged 6-12 years that gives children a "voice" in their care. With its child-friendly interface, Sisom helps children report their symptoms and problems, enabling health care professionals to better understand the children's concerns and respond with appropriate care. The main theme in Sisom is a discovery journey among islands that the child can visit together with a personalized avatar. Sisom uses spoken text, sounds, animations, and intuitively meaningful metaphors and pictures to represent symptoms and problems, allowing even younger children who cannot yet read to understand and communicate [16].

Sisom is available in Norwegian, US and UK English, Spanish, Greek, and French. The previous versions of Sisom have been successfully tested in Norway and the United States, showing significant improvements in patient care and patient-provider communication: twice as many symptoms and problems were addressed when Sisom was used in pediatric consultations, without increasing consultation time [17]. Children also received significantly more information from the physicians, were asked more follow-up questions by the pediatric nurses, the parents and health care professionals communicated more often directly with the children, and the children participated more with information and in illness-related discussions more often [17]. The original version of Sisom has been widely tested for its usability [16-20]. However, because of technological advances and widespread use of mobile devices Sisom had to be redesigned to better meet the needs of children of today and their demands on aesthetics and usability of mobile apps available on mobile phones and tablets. The aim of this study was thus to redesign Sisom for use on mobile devices and to validate and adapt it for use in a Swedish population of children with cancer.

Methods

Design

The user-experience design [21] for redesigning and validating a revised version of Sisom included (1) forward-backward translation, (2) evaluation of the understanding of Sisom's symptom statements, and (3) iterative low- and high-fidelity evaluation [22], in a Swedish context with healthy children, children with experiences of cancer treatment and their parents, and pediatric nurses during a 10-month period in 2014-2015.

Participants

For the forward-backward translation and the evaluation of the understanding of Sisom's symptom statements, purposive sampling was used to recruit Swedish translators (n=4), Norwegian translators (n=2), pediatric nurses working with the care of children with cancer (n=2), and healthy children (n=2). For the low- and high-fidelity evaluation, purposive sampling was used to recruit children with experiences of cancer treatment (n=5) and their parents (n=5), the same pediatric nurses (n=2) as previously involved, and healthy children (n=5) with some experience in medical treatment (eg, surgery, vaccination, treatment of eczema). The healthy children, who were recruited from academic researchers' families, were used as proxies for children with experiences of cancer treatment, for evaluation of general understanding of content and usability that was not expected to be dependent on a prior experience of cancer treatment. The user-experience design could pose an impossible burden on children with experiences of cancer treatment. Therefore, the use of proxies was important in order to conserve

access to a limited selection of children with a unique experience of cancer treatment to evaluate very general aspects of content, aesthetics, and usability. The pediatric nurses were recruited from a pediatric clinic in southern Sweden and were important participants because of their experiences and knowledge of caring for children with cancer with different symptoms or problems and also to judge if these symptoms or problems described in Sisom were relevant in a Swedish context. The children with experiences of cancer treatment and their parents were recruited by the pediatric nurses based on their judgment on whether the child felt well enough to ask for participation in the study. All children were selected based on sex, age (6-12 years), and literacy skills in Swedish. The child and family characteristics are presented in Table 1.

The Original Version of Sisom

The original version of Sisom was an interactive computer-based communication tool with spoken texts, sounds, animations, and intuitively meaningful metaphors and pictures to represent symptoms and problems. Together with a self-selected avatar, the child sets out on a virtual journey from island to island (in total 5 islands: “At the hospital,” “About managing things,” “My body,” “Thoughts and feelings,” and “Things one can be afraid of”). Symptoms and problems (n=82) were placed on different islands: for example, physical symptoms were placed on the “My body” island, psychological problems on the “Thoughts and feelings” island, and so on.

Every symptom and problem was represented by an animation, a brief statement (also spoken by a cartoon nurse), and the assessment item “How much of a problem?” [16]. The child responded by selecting the level of severity on a 5-point Likert scale with cartoon faces (differently colored smileys) complemented in writing with “Not at all,” “A little,” “Some,” “A lot,” and “Don’t know.” In addition, the child could specify areas of pain, bruises, and rash on a body map [19]. The symptoms and problems used in Sisom were identified in a literature review [23] and the development of Sisom was carried out with clinicians (ie, physicians, nurses, psychologists), parents of children with cancer, healthy children, and children with cancer. Details of this development are described elsewhere [15,16].

Data Collection and Procedure

The redesign of Sisom into Sisom 2 and adaptation to a Swedish context began with translation, where a Swedish version of Sisom was constructed through a forward-backward translation procedure [24,25]. Four persons with university degree, native Swedish speakers fluent in both Norwegian and Swedish, translated from Norwegian to Swedish. Then 2 persons with university degree, native Norwegian speakers fluent in both Norwegian and Swedish, and at that time with a limited knowledge of the original version of Sisom, retranslated to Norwegian. The backward translation, from Swedish to Norwegian, was used to improve the quality of the final Swedish version [24,25]. In the next step, healthy children and pediatric nurses contributed with an evaluation of the understanding of Sisom's symptom statements, in order to make the final translation culturally representative and child-friendly. This procedure was performed to also assess the level of comprehensibility and conceptual equivalence of the translation, to evaluate translation alternatives, to elicit any symptom statements that were difficult to understand at a conceptual level, and to identify symptom statements that could cause confusion [24,25]. A few minor differences emerged in the backward translation in comparison with the original version of Sisom and the evaluation of the understanding of Sisom symptom statements. These differences were more related to changes to a more child-friendly wording than a change of content. All differences were discussed in the research group and modified to achieve comprehensibility and conceptual equivalence [26].

In the next stage, iterative low- and high-fidelity evaluations were performed, consisting of 6 steps: (1) observation and evaluation where children were instructed to think aloud [27] when using Sisom; (2) semistructured interviews with each child and the parents separately, about what they liked and disliked about the design and aesthetics, the symptom statements, and assessment items posed; (3) paper screenshots of Sisom on which children were asked to draw or write suggestions for improvement of the graphics and pictures in Sisom; (4) documentation of technical problems; (5) compilation of use evaluation; and (6) data-driven refinement of the service toward Sisom 2. In steps 1-3 healthy children, children with cancer and their parents, and pediatric nurses participated, which resulted in a total number of 55 data collection encounters (see Table 2). These 3 steps were all audiotaped. Findings were discussed in the research team between the meetings with the children, and the latter’s ideas and opinions from steps 1-3 were used to guide revisions made by a graphical designer and a system developer in the team (steps 4-6). They drew the children’s ideas in the next rough versions of Sisom that were given back to the children for evaluation and further elaboration in the next meeting. This low- and high-fidelity evaluation (steps 1-6) was iterated until no further changes or improvements were identified by the participants or the researchers, resulting in 4 cycles in total (Figure 1).

Table 1. Child and family characteristics.

Characteristics		Healthy children	Children with cancer
Age in years, mean (SD)		8.4 (1.82)	8.2 (1.64)
Family household size, mean (SD)		4.8 (0.45)	5 (1.00)
Characteristics of the children, n (%)[a]			
Sex			
	Male	3 (60)	3 (60)
	Female	2 (40)	2 (40)
Cancer diagnosis			
	Acute lymphoblastic leukemia		2 (40)
	Brain tumor		1 (20)
	Ewing sarcoma		1 (20)
	Wilms tumor		1 (20)
Time since diagnosis, years			
	<2		1 (20)
	2-3		1 (20)
	4-5		3 (60)
Time since completed all cancer treatment, years			
	<1		1 (20)
	1-2		4 (80)
Parents view of child's health status			
	Excellent		3 (60)
	Very good		2 (40)
	Good		0 (0)
	Fair		0 (0)
	Poor		0 (0)
Characteristics of the families, n (%)[b]			
Parental marital status			
	Married/cohabitation	6 (100)	10 (100)
	Divorced/separated	0 (0)	0 (0)
	Widowed	0 (0)	0 (0)
Parental education			
	< High school	0 (0)	1 (10)
	High school	1 (17)	7 (70)
	University	5 (83)	2 (20)

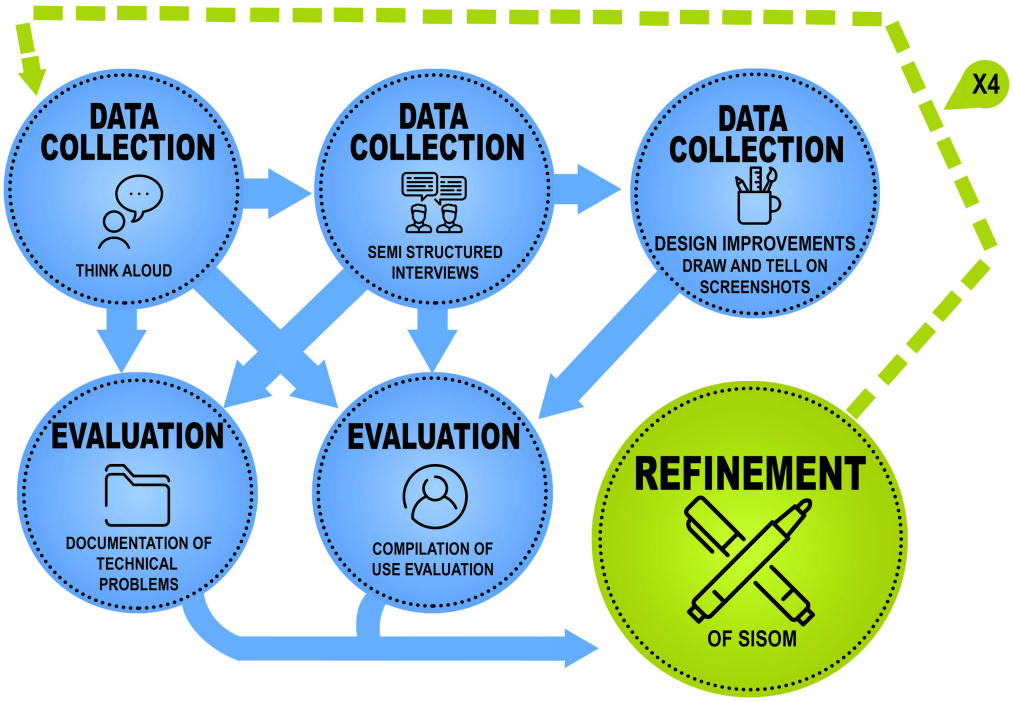
[a] Healthy children, n=5; children with cancer, n=5.

[b] Parents of healthy children, n=6; parents of children with cancer, n=10.

Table 2. Participants and the number of participants in each of the 4 cycles in the iterative low- and high-fidelity evaluation of Sisom.

Participants	Cycles, n				Total number of data collection encounters
	1	2	3	4	
3 boys (7-10 years) who have been treated for cancer	3	3	3	3	12
2 girls (6-9 years) who have been treated for cancer	0	2	1	1	4
3 healthy boys (6-11 years)	3	3	3	2	11
2 healthy girls (8-9 years)	2	2	2	1	7
5 parents of children who have been treated for cancer	3	5	4	4	16
2 pediatric nurses	2	2	0	1	5
Total sum	13	17	13	12	55

Figure 1. Outline of the iterative low- and high-fidelity evaluation process for redesign of Sisom, which resulted in 4 cycles in total.



Data Analysis

The data (interviews, observations, and drawings) from the iterative low- and high-fidelity evaluation (steps 1-3) were evaluated by a qualitative content analysis [28]. This entails that each interview was listened to several times for familiarization and for gaining an overall impression of the data. Words or statements that related to the same central meaning were referred to as a meaning unit. The relationships between the meaning units, the observations, and the drawings were clustered and connected together. The analysis process resulted in 3 categories on a manifest level: evaluation of content, evaluation of aesthetics, and evaluation of usability. Representative quotations and drawings from the children are used in the results to illustrate the data in the categories. The analysis was carried out by the first author and evaluated by means of discussions between all the authors during the analysis process. Participant characteristics were analyzed with descriptive statistics using SPSS version 20.

Ethical Considerations

All study procedures were performed with ethical permission from the regional ethical board in Lund (dnr: 2011-307). The children's participation in the study was discussed with both parents and the child. The children, parents, and pediatric nurses were informed verbally and in writing about the study and that their participation was voluntary. They were assured confidentiality and that they could withdraw their consent to participate at any time without having to justify the reason and without it having any effect on their care.

Results

The results from the redesign and validation process included 3 categories: evaluation of content, evaluation of aesthetics, and evaluation of usability that influenced the new version of Sisom.

Evaluation of Content

When the children, parents, and pediatric nurses at the first low-fidelity evaluation of content reviewed and discussed the Swedish texts, most symptom statements were found to be appropriately adjusted to linguistic and cultural context, but some symptom statements needed further clarification. The parents and pediatric nurses also questioned why the symptom statements had such a negative or risk-accented phrasing, such as “Getting a tube feels awful” or “Sleeping problems.” They wanted, instead, that the symptom statements be more neutral and that children could use the cartoon smiley faces on the Likert scale to determine whether it was unpleasant or not and to rate the degree of severity (Figure 2).

The parents expressed that a modification of the symptom statements toward a more salutogenic perspective was important because when their child was ill they tried to focus on what their child could do and what generated joy in their lives. It had been important for them to not emphasize or focus on all the problems and difficulties that the child had. The symptom statements were thus modified to a more salutogenic and positive orientation instead of the perceived problem-focused orientation. This modification also entailed that the assessment item posed related to the Likert scale was adjusted from “How much of a problem?” to “How is this for you?”. Children could then choose from “No problem,” “A little,” “Some,” “A lot,” and “Don’t know” (Figure 3); that is, from “Anesthesia feels awful” and “How much of a problem?” to just “To get anesthesia” and “How is this for you?”. The other symptom statements and assessment items in Sisom 2 were rephrased according to this.

In the second evaluation, it became apparent that the children did not read the assessment item “How is this for you?”; they just read and/or listened to the speaker voice that only said the symptom statement. This generated confusion and questions about how the symptom statements should be interpreted. These assessment items were evaluated and further developed at a third evaluation with children and parents. In addition to suggestions for minor revisions this interaction also showed that it was important that the assessment items did not begin in the same way, for example, “How is this for you...” because it was then perceived as being tedious to answer the assessment items. The varying of the assessment items also entailed changes to the first response on the Likert scale, from “No problem” to “No/No problem” (Figure 4).

In addition, some animations contained 2 symptoms in 1 symptom statement (2 of 82), which reduced clarity. Therefore, these animations were divided into 1 symptom per symptom statement. The parents and the pediatric nurses also questioned whether some symptom statements (6 of 82) were relevant, such as “Act younger than I am.” They maintained that the children were not aware of their behavior in that way. The pediatric nurses and parents also suggested a new assessment item, “How is it for you to get a needle into the port?”, because this was a common procedure in Swedish hospitals. All inputs led to the symptom statements being revised and finally rephrased into 84 assessment items.

At the final high-fidelity evaluation, the children and parents were able to see the final result and how they had contributed to the development and validation of the language and content in Sisom 2. The children confirmed that they found it easier to understand what was asked and how they should respond when the symptoms were presented as assessment items rather than as symptom statements. Some assessment items in Sisom 2 were more generic and applicable in many situations (eg, headaches) and others were more cancer specific (eg, hair loss), but this approach was not perceived as a problem for the children. If the children had no experience of what was presented by the assessment item, they answered it with the smiley “Don't know.” The participants judged the assessment items as relevant and easy to understand, indicating good face and content validity.

Figure 2. The parents and the pediatric nurses suggested that the statements should be more neutral than in this picture of the first version of Sisom 2.

Figure 3. The parents and the pediatric nurses suggested that the statements should be more salutogenic and the statement was therefore adjusted from "Anesthesia feels awful" to just "To get anesthesia" and the assessment item was adjusted from "How much of a problem?" to "How is this for you?".

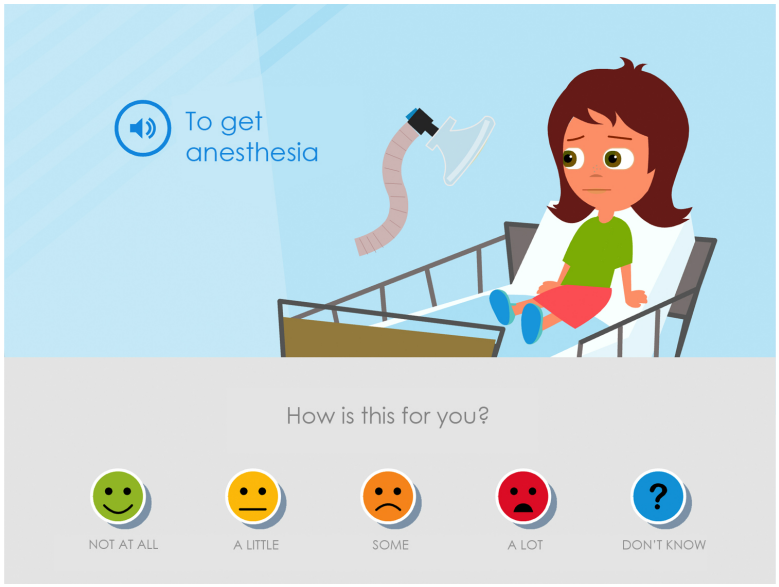
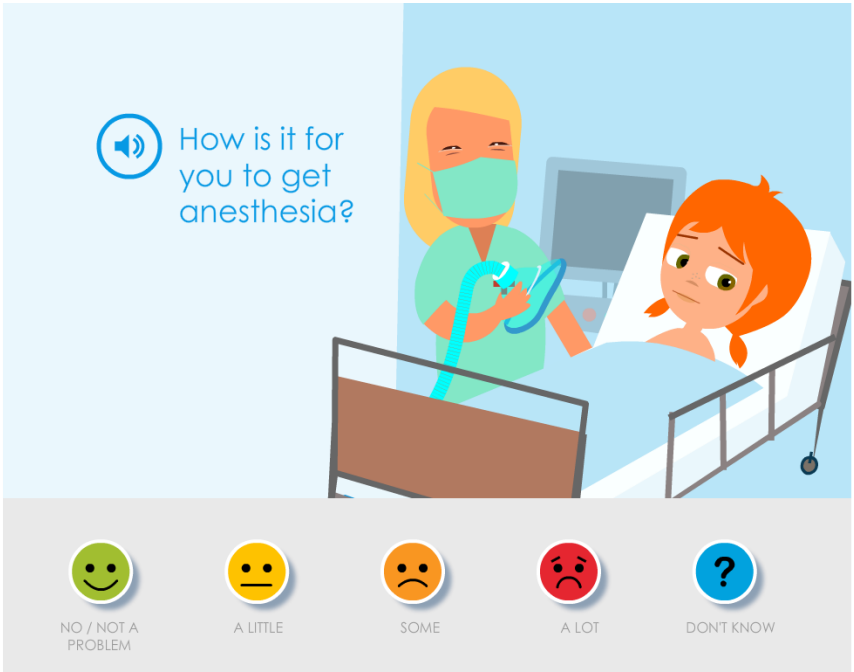


Figure 4. The picture shows the final outcome based on the children's and parents' suggestions that there should only be a single assessment item in a picture.



Evaluation of Aesthetics

At the first low-fidelity evaluation of aesthetics, children liked the fact that they were allowed to participate through a child avatar in Sisom and enjoyed the concept of a boat that could travel between different islands. The adjustment of the visual design to suit an iPad, rather than a desktop computer, led to them seeing a potential for choosing different environments for the avatar to travel in. Examples of these are driving a water scooter, car, motorcycle, airplane, tractor, train, kickboard, or riding a bike or a horse, or being a dinosaur, princess, hairdresser, or various animals, or completely changing the environment into a jungle, zoo, farm, and so on. The children would also have liked the opportunity to choose various attributes for the avatar, such as a shawl, a beanie, or a cap and various hairstyles, which was accommodated. Some parents wondered whether it was important that the children had to choose to be a boy or a girl in the introduction. They pointed out that the avatar was gender neutral and that the children themselves could determine what the avatar would look like, with the help of skin color, headdress, and clothes. The feedback on attributes for the avatar was incorporated in the visual design, whereas the suggestions for different environments and a gender-neutral avatar composition were considered to be beyond the scope of the ambitions for Sisom 2. These could, however, be important improvements for future versions of Sisom and be used as functionalities that can drive children's intrinsic motivation to use Sisom over longer periods of time.

The children did not think Sisom was as fun as an ordinary iPad game at the first low-fidelity evaluation. They said, "The colors in Sisom are boring and gloomy." The children and parents also thought it was important that positive and exciting things appeared. They preferred brighter colors and more details, such as fishes in the sea, birds flying, clouds, crabs on the beaches, a sand castle, an ambulance and helicopter outside the hospital, and so on (Figure 5). The children would also like to hear background noises from the birds and other things that appeared visually. These suggestions were embedded in the next version of Sisom.

At the second evaluation the children and parents thought that the animations in Sisom 2 had become much better and that the colors were happier and brighter. They liked that their suggestions had been taken into account when changes in Sisom had been made (Figure 6).

At the first low-fidelity evaluation it emerged that the children, who had not read the text beneath the smileys, had not understood the difference between the smileys in orange and red in the Likert scale. They thought the only difference was that the mouth was open in the red smiley. At the next evaluation the mouth of the red smiley was changed to be sadder and this was better according to both children and parents (Figures 2 and 7).

On the "At the hospital" island the symptoms contained medical supplies such as a syringe, a tube, and so on. In order to avoid the children being intimidated by this equipment the design and programming had been simplified so that these objects appeared as symbols detached from their proper use in the animations. The children suggested, however, that the objects ought to be integrated into the animations and involve the avatar instead of being placed "in the air" beside the avatar, for example, as in the picture "Disgusting to get a feeding tube" (Figure 8).

The children also thought it would be better if some animations, for example, the picture with the symptom statement "To get shots," were illustrated by a cartoon nurse holding the shots and with the nurse standing beside the avatar. The children also thought that there should be a nurse or a doctor in the treatment room at the hospital (Figure 9) and a teacher in the classroom at school. For the next evaluations, these changes were made iteratively until the children thought it was better and clearer (Figure 9).

At each evaluation, children were very good at detecting whether there were missing details in the pictures. For example, in the animation for "Eat and drink," a child thought there should be a missing pizza slice in the box because there was a pizza slice on the plate. Another example was that children thought that the animation for "Often thirsty" would have been better if the avatar drank from several glasses instead of from the pitcher. The children and parents also suggested new topics that they thought should be included in Sisom 2. One example was to include a schoolyard at the school (Figure 10), because the children had sometimes experienced problems during breaks between lessons.

In the first version of the "My body" island, all parents thought that one of the sandmen looked "grotesque," especially since the island was concerned with problems that the children had with their bodies. The parents wondered how a child, who had experienced surgery to amputate a part of the body, would feel when answering these assessment items. None of the children reacted to the sandman's appearance, but when they saw the modified version based on the parents' input, they thought that it was much better and that the new details "were cool."

When the children answered the assessment items about "Pain and discomfort," they were considerably more engaged and happy with the way they could report their experiences. These assessment items were answered by indicating areas of pain, bruises, and rashes on a body map using color-specific icons (Figure 11). The responses of the children and parents were similar to previous comments about them preferring variations in how the children could answer assessment items.

There were 84 symptoms in the final version of Sisom 2, which were individually represented by assessment items and animations, and more than 100 large or small visual modifications had been made based on the participants' views. At the concluding high-fidelity evaluation when the children compared Sisom 2 with other games on their own iPads, they thought the animations in Sisom 2 should remain being on a simpler level and not so realistic. If Sisom 2 had been more lifelike, then many images, such as removing stitches, would be too frightening. The children also thought that it was easier to answer the assessment items in Sisom 2 compared with answering the same assessment items in a paper questionnaire or orally, because in Sisom 2 they received guidance from the animations on how to interpret the assessment items.

Figure 5. The children suggested that the pictures in Sisom should have more details. Left: an example of what a child drew on a screenshot; Right: the final version in Sisom 2.

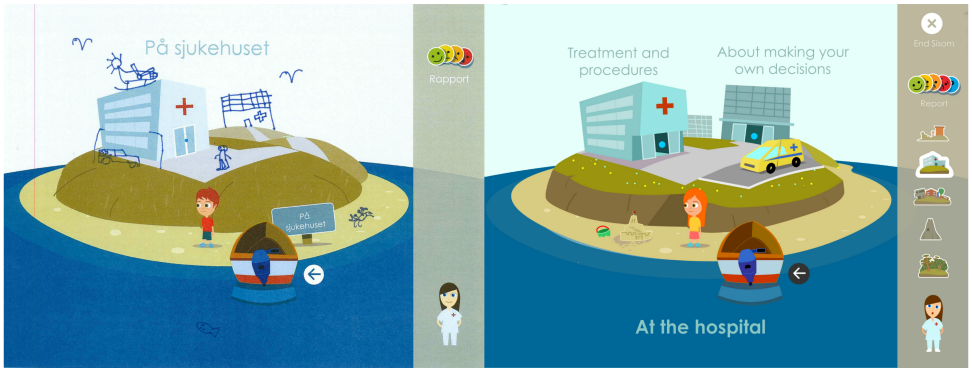


Figure 6. This start view shows the refinements based on the children's suggestions of brighter colors and more details.

Figure 7. This picture shows the refinements based on the children and parents' suggestions to change the open mouth of the red smiley to a more sad illustration.

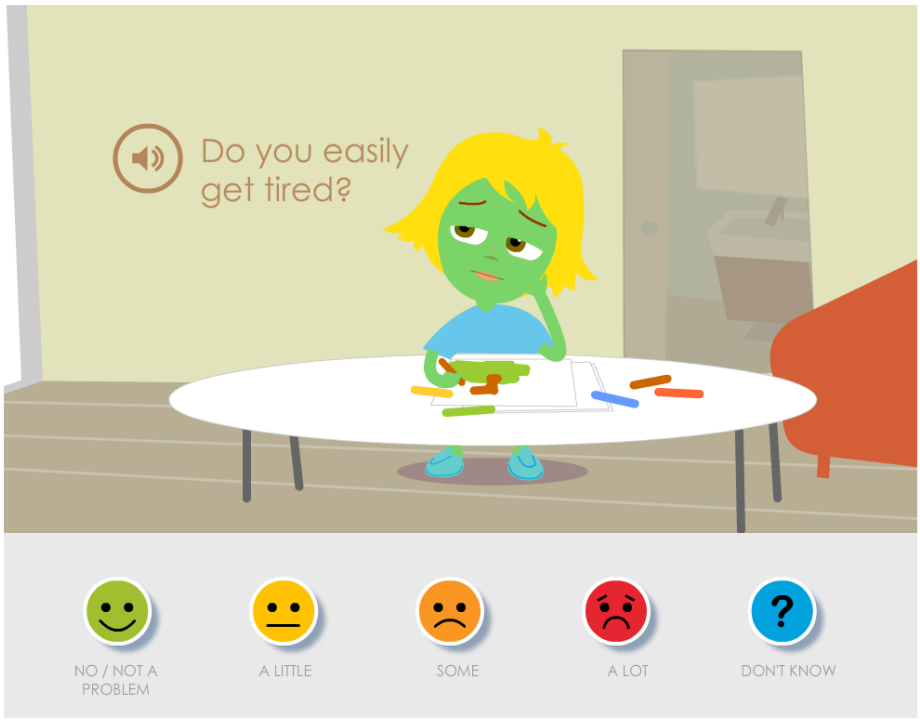


Figure 8. The children wanted the object in the pictures to be integrated with the avatar in the animation and not be "in the air" beside the avatar. Left: an example of what a child drew on a screenshot; Right: the final version in Sisom 2.

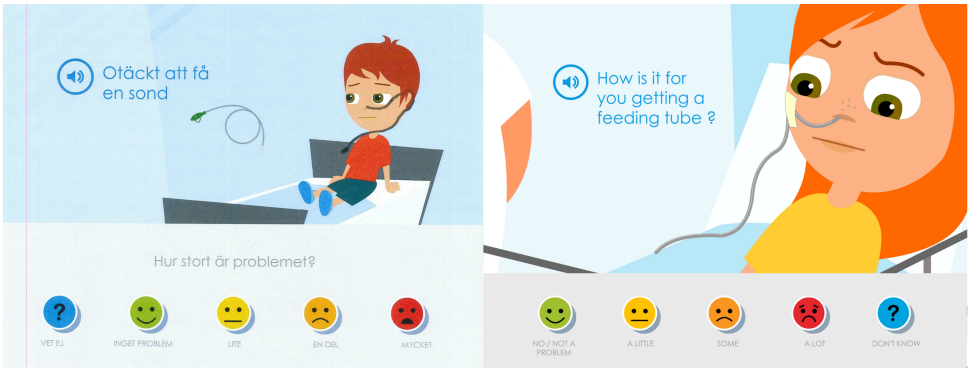


Figure 9. The children suggested that pictures at the hospital should include a nurse or a doctor. Left: an example of what a child drew on a screenshot; Right: the final version in Sisom 2.

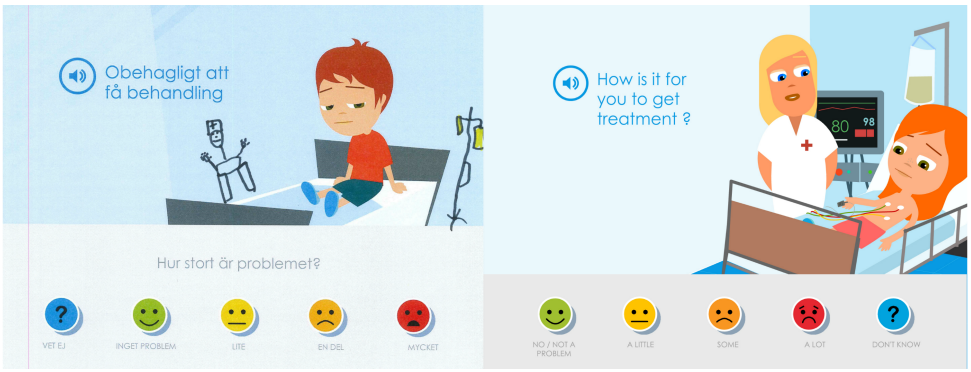
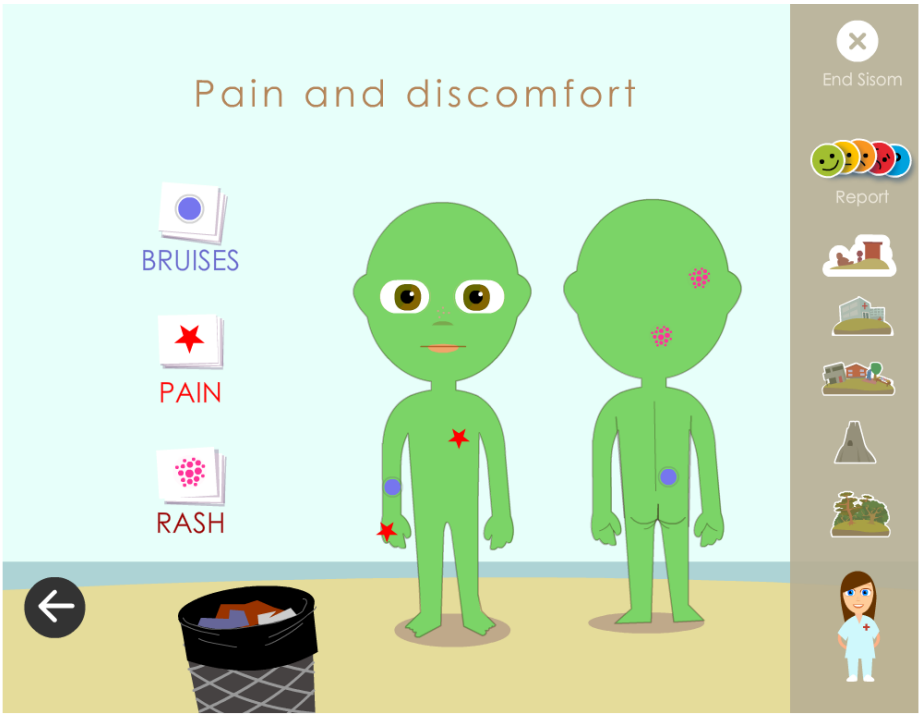


Figure 10. The children suggested that a schoolyard should be included at the school. Left: an example of what a child drew on a screenshot; Right: the final version in Sisom 2.

Figure 11. The children appreciated being able to answer by indicating areas of pain, bruises, and rashes on a body map.



Evaluation of Usability

At the first low-fidelity evaluation of usability, the children and parents requested an integration of more support and instructions in order to reduce uncertainties in understanding statements and animations correctly and to increase the usability. As verbal and visual support and instructions were inserted, both children and parents thought clarity was increased. However, the need for instructions decreased as the children became familiar with the system. One child said, “Can’t stand to listening to the instructions all the time.” They thought it was a major improvement, at the next evaluation, when the verbal instructions appeared only once after they had answered all assessment items on an island. The voice representing the cartoon nurse was of great importance for the children and parents’ experiences of Sisom 2. At the first evaluations they wished for a happier and more stimulating voice, and after the revision they thought that the voice sounded less sad and more “Normal, like someone you know.”

The children with experiences of cancer treatment, the parents, and pediatric nurses thought that the children would not have had the strength or concentration to manage to answer all assessment items in Sisom 2 in some phases of the disease and treatment. They thought it was thus important that answers to the assessment items in Sisom 2 could be saved and that they could pause and continue with the remaining assessment items later on without having to start from the beginning.

The comments from the parents and pediatric nurses together with the researchers’ observations about how the children navigated in Sisom contributed to technical difficulties and bugs being identified and resolved. All participants then acknowledged the usability and qualities of using the final version of Sisom 2 in the clinical work at pediatric clinics at the concluding high-fidelity evaluation. They thought that the system was usable and would consider using it if offered. Both pediatric nurses and parents considered the final versions of the assessment items applicable for children with many different conditions and not cancer diagnosis specific.

Discussion

New mobile devices provide powerful tools for children in health care, with the potential for paying attention to their needs. This can change the communication pattern between children and health care professionals, as well as strengthen children’s empowerment [11,29]. We, therefore, redesigned and validated Sisom in order to meet the new opportunities for adaptation to mobile devices, with the purpose of it being applied as a user-friendly assessment and communication tool in pediatric care. The user-experience approach to redesign and validate Sisom in this study was guided by the evaluation of content, aesthetics, and usability.

As found in earlier research [30], the children in our study described that it was easier and more fun to answer assessment items in an animated application than in a paper questionnaire or orally. Earlier research has shown that children’s experiences of being asked questions in hospital settings are generally not positive, because they are only asked a few specific questions, primarily about symptoms, and then the health care professionals discuss the issue with their parents [7]. Children’s preferences for participation vary and it is important that their views are sought on how they want to communicate and be involved in their own health care [7,31]. Our intention is that Sisom 2 will be a communication tool that is adapted to the new technology in order to capture children’s own needs and preferences in health care.

Children from a very young age are now generally comfortable with mobile devices, such as an iPad, mobile phone, and tablet

devices [32,33]. However, how the language is used in the instructions and tasks during the play is important because this may affect children's opportunities to understand the instructions and tasks that are given to them [34,35]. A mixture of audio and textual instructions in the mobile devices seems to be most suitable to support the children's different levels of ability and preference [36,37]. In this study, major improvements were made regarding both the verbal instruction of how to navigate and how to ask assessment items in Sisom 2 to the child. In the original version of Sisom the assessment items were pronounced as symptom statements and then the children answered these symptom statements based on the assessment item "How much of a problem?" The children had difficulties understanding this way of answering because of confusion as to how the symptom statement and the assessment items were connected. This led to Sisom 2 containing only 1 assessment item for each symptom and the assessment item is the same in both written text and in the audio from the cartoon nurse. Previous research has shown that young schoolchildren prefer statements rather than assessment items [38]; however, the biggest problem in our study was that the symptom contained both a symptom statement and an assessment item and that the written text and sounds not were the same. The assessment items were also changed in order to be more neutral to avoid assumptions that the symptom already was a problem. The reason for the suggested improvements of the assessment items was to not take for granted that the symptom was a problem for the child. It is more appropriate to ask the child how he or she feels about the symptom. Having a more salutogenic perspective in Sisom 2 could provide health care professionals with the possibility of paying attention to the children's own defined health experiences, instead of focusing on predefined problems related to the disease [39]. The modification of problem-oriented statements to more salutogenic or neutral assessment items in Sisom 2 is in line with the recommendation that the language in health care should shift from disease to health in order to improve the conditions for empowering patients [40-42].

Children want apps on mobile devices to be appealing and fun to use [22,43]. In this study the children suggested substantial improvements in the colors, sounds, and animations in order to have more fun when answering the assessment items. The children's preferences on the aesthetics in the digital environment seemed to be equivalent to their preferences in the hospital environment. In earlier research children described that brighter colors in the hospital environment contribute to positive emotions and darker colors contribute to negative and stressed emotions [44-46]. Both visual and auditory effects were important to maintain the children's interest and motivate them to go through the whole Sisom 2. However, the animations should be of a simpler nature because otherwise some assessment items concerning difficult disease-related issues, for example, if they were afraid of dying, could be perceived as scary or as inappropriate. Other preferences from the children was that they thought it would be fun if they could travel around in Sisom in different ways and if the environment could change to other sceneries other than traveling by boat between islands. Such alternatives were seen as ways of increasing enthusiasm and intrinsic motivation to respond to Sisom 2 several times and during a period of illness. This is an important aspect for further development of Sisom 2, for uses in settings where motivation is a factor that can limit usefulness and feasible implementation; however, this was beyond the scope of this study and for the redesign of Sisom.

The final version of Sisom 2 made it technically feasible for the child to pause "the game" if they did not manage to complete all assessment items at the same time. The data that they had already filled in were stored. This is an important technical improvement because one common problem for children with cancer, as well for other diagnoses, is increased fatigue during the treatment [47-50]. Many children in health care have complex communication needs, which require technical support in order to convey how they feel. We anticipate that the redesign of Sisom 2 allows for more generic and non–diagnosis-specific use. Studies of Sisom 2 thus need to evaluate how children (aged 6-12 years) with different life-threatening, lifelong, or prolonged diseases find Sisom 2 usable as an interactive assessment and communication tool. There is also a need to investigate how Sisom 2 as a new digital service in pediatric care can transform the way health care professionals deliver health care as well as if Sisom 2 can strengthen children's participation in their own care.

Methodological Considerations

An important challenge in research with children is to find appropriate ways for engaging and creating opportunities for children to have genuine influence on the research process [51]. Children in our study have added valuable views and quality of ideas regarding content, aesthetics, and usability that have genuinely influenced the design of Sisom 2. Involving children throughout the low- and high-fidelity evaluation was considered as essential for the outcomes.

A key factor in any evaluation is the quality of the target group representation during investigations. In this study we have involved fairly few children, parents, and health care professionals in repeated encounters. On the other hand their involvement was extensive and together they represented healthy children with some experiences of medical treatment, children with experiences of cancer treatment, their parents, and pediatric nurses and thus contributed with valuable different experiences and perspectives. Research has shown that 80% of all usability problems are detected with as few as 4-5 participants [52], and we are therefore inclined to believe that the number of participants in our study was sufficient to address the usability issues we wanted to evaluate. The healthy children with some experiences of medical treatment were used as proxies for children with experiences of cancer treatment and were recruited from academic researchers' families, which may be a bias.

Ruland et al [16] have shown that healthy children can only partially conceptualize what it is like suffering from a serious illness, and thus the degree to which they can serve as proxies in participatory design and evaluations is limited. However, Ruland et al [16] thought that personal experiences could be an important factor for valuable design contributions. All the healthy children in this study had some experience of medical treatment (eg, surgery, vaccination, treatment of eczema) and their descriptions of the general aspects of content, aesthetics, and usability in Sisom 2 were compatible with the description

from the children with experiences of cancer treatment. Another important design issue is that all the children were white and ethnically Swedish. Therefore, an important next step is to refine and adjust Sisom 2 to children from different ethnic backgrounds.

One aspect that was missing, however, was that the parents' perspectives were almost entirely presented by the mothers, and the fathers were consulted by the mothers either only occasionally or rarely and briefly participated in the discussions. We do not know how important more contribution of the fathers or children during ongoing treatment at the hospital setting could have been. Children with cancer who were involved in ongoing treatment were not included in the study because of ethical considerations and because they were often included in several different studies.

Conclusions

In conclusion, this study illuminates the process of using a user-experience design with children to redesign and validate the interactive assessment and communication tool Sisom, and it describes how the evaluation of content, aesthetics, and usability resulted in a revised version, Sisom 2. Involving children throughout this research process was essential for including valuable views relevant for the user group and to ascertain quality of ideas. These contributions genuinely influenced the design of Sisom 2. The modification of problem-oriented statements to more salutogenic assessment items was the most important revision of the content in Sisom 2. Parents and pediatric nurses considered the revised assessment items to be less diagnosis specific. The evaluation of the aesthetics resulted in brighter colors and more positive and exciting details in the animations. The evaluation of usability improved the verbal instructions for how to navigate, while also enabling the answers to assessment items in Sisom 2 to be saved so that the children could pause and continue to answer the remaining assessment items at a later stage. All participants confirmed the usability and qualities of using the final version of Sisom 2. Future research should be directed toward studying the implementation of Sisom 2 in various clinical practice contexts and its effects on patient care and outcomes.

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Conflicts of Interest

None declared.

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Original Paper

Theory-Based Design and Development of a Socially Connected, Gamified Mobile App for Men About Breastfeeding (Milk Man)

Becky K White[1], BSc, GradCert; Annegret Martin[1], BA, GradDip; James A White[2], BSocSc, GradDip, PhD; Sharyn K Burns[1,3], BEd, PGDip, DipPhyHlthEd, MPH, PhD; Bruce R Maycock[1,3], BPE, PGrad Dip, MEd, PhD; Roslyn C Giglia[1,4], BAppSc, GradDipDiet, MPH, PhD; Jane A Scott[1,3], BAppSc, GradDipDiet, MPH, PhD

[1]School of Public Health, Curtin University, Perth, Australia

[2]Reach Health Promotion Innovations, Perth, Australia

[3]Collaboration for Evidence, Research and Impact in Public Health (CERIPH), Curtin University, Perth, Australia

[4]Telethon Kids Institute, University of Western Australia, Perth, Australia

Corresponding Author:
Jane A Scott, BAppSc, GradDipDiet, MPH, PhD
School of Public Health
Curtin University
GPO Box U1987
Bentley
Perth, 6845
Australia
Phone: 61 8 9266 9050
Fax: 61 8 9266 2958
Email: jane.scott@curtin.edu.au

Abstract

Background: Despite evidence of the benefits of breastfeeding, <15% of Australian babies are exclusively breastfed to the recommended 6 months. The support of the father is one of the most important factors in breastfeeding success, and targeting breastfeeding interventions to the father has been a successful strategy in previous research. Mobile technology offers unique opportunities to engage and reach populations to enhance health literacy and healthy behavior.

Objective: The objective of our study was to use previous research, formative evaluation, and behavior change theory to develop the first evidence-based breastfeeding app targeted at men. We designed the app to provide men with social support and information aiming to increase the support men can offer their breastfeeding partners.

Methods: We used social cognitive theory to design and develop the Milk Man app through stages of formative research, testing, and iteration. We held focus groups with new and expectant fathers (n=18), as well as health professionals (n=16), and used qualitative data to inform the design and development of the app. We tested a prototype with fathers (n=4) via a think-aloud study and the completion of the Mobile Application Rating Scale (MARS).

Results: Fathers and health professionals provided input through the focus groups that informed the app development. The think-aloud walkthroughs identified 6 areas of functionality and usability to be addressed, including the addition of a tutorial, increased size of text and icons, and greater personalization. Testers rated the app highly, and the average MARS score for the app was 4.3 out of 5.

Conclusions: To our knowledge, Milk Man is the first breastfeeding app targeted specifically at men. The development of Milk Man followed a best practice approach, including the involvement of a multidisciplinary team and grounding in behavior change theory. It tested well with end users during development. Milk Man is currently being trialed as part of the Parent Infant Feeding Initiative (ACTRN12614000605695).

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KEYWORDS

mHealth; smartphone; mobile phone; app; breastfeeding; fathers; gamification; social connectivity

Introduction

Breastfeeding

Breastfeeding is universally recognized as the optimal way for babies to receive nutrition, and breastfeeding offers many well-documented health benefits for both mother and baby [1-4]. Despite concerted effort in policy, research, and community and hospital practice, breastfeeding rates in Australia at 6 months, and in particular rates of exclusive breastfeeding, remain low [5]. Breastfeeding initiation rates are generally good, with 96% of Australian women initiating breastfeeding. However, rates decline steadily thereafter, with only 15% of babies exclusively breastfed at 5 months [5].

Targeting Fathers

The influence of the father has been identified as one of the most significant factors influencing the breastfeeding behavior of the mother [6-10]. Scott et al reported that a woman's partner has an important influence on the mother's decision to initiate and to continue breastfeeding [11]. These findings were reinforced in 2015 with data from the Australian Infant Feeding Survey, which found that multiple factors have an impact on breastfeeding cessation, with the most influential factors being the partner's views, the use of pacifiers, and maternal obesity [6].

Relatively few father-focused breastfeeding interventions have robustly evaluated breastfeeding outcomes using a randomized controlled trial (RCT) design. However, the Fathers Infant Feeding Initiative (FIFI), conducted by members of our team, trialed a male-facilitated antenatal class for expectant fathers and a follow up social support component consisting of age-relevant information being mailed out to participants [12]. The FIFI RCT reported a significant difference between intervention and control groups in the percentage of babies who received any breastmilk at 6 weeks of age (intervention: 81.6%, control: 75.2%) [12]. The researchers recommended extending the study to 6 months and separating the social support intervention from the male facilitator-led antenatal sessions to measure the relative effect. The study also reported that fathers expressed a preference for Internet, email, and video to be used as a basis for the delivery of information [13].

Mothers have reported that partner support makes a difference to their confidence, as well as helping them to achieve their breastfeeding goals [14,15], and fathers typically indicate they are supportive of breastfeeding and want to be involved [13,14,16,17]. Involving fathers and increasing their support for breastfeeding has been recommended repeatedly in the literature [10,11,16-19]. However, despite fathers generally being supportive of breastfeeding, the literature highlights several factors that can affect the level of support they are equipped to offer. These factors include social support, knowledge, empowerment, and other specific barriers (see Textbox 1 [13,14,16,17,19-29]).

Textbox 1. Factors affecting the support fathers offer to their breastfeeding partners.

Social support [13,14,16,20-23]

- Insufficient social support
- Frequent exclusion from family support programs
- Lack of opportunities to learn and share
- Lack of peer support

Gaps in knowledge [13,14,16,17,19,22,24,25]

- Expectations about breastfeeding, bonding with baby, and about how life changes after baby arrives
- Health and other benefits of breastfeeding
- Practical suggestions to help family
- Professional services available, for mothers and fathers

Empowerment [14,16,19,20,22,26]

- Lack of recognition of paternal role
- Lack of understanding of importance of paternal support for breastfeeding
- Need for more information and practical advice on how men can better support their family

Barriers [14,16,17,22,23,26-29]

- Concerns around having to postpone bonding with baby until breastfeeding has finished, or around other ways to bond with baby besides feeding
- Public breastfeeding
- Feeling left out of the relationship (with their partner and with the baby)

Mobile Technology and Health Promotion

While specific recommendations from the FIFI study focused on the use of the Internet and DVDs, the technological landscape has changed markedly since the FIFI study was implemented in 2008. Smartphone usage is now virtually ubiquitous in Australia. In July 2014, Deloitte estimated that 81% of Australians aged 14 years and over owned a smartphone [30]. App usage is also prevalent, with the Australian Communications and Media Authority finding that 75% of Australian smartphone users had downloaded an app to their smartphone in a 6-month period [31]. Data from the United States in 2014 revealed that Android and iOS smartphone users were spending 65% more time using apps than they had 2 years previously, equating to 30 hours and 15 minutes each month per user [32]. Australians now spend more time accessing the Internet from smartphones than they do from desktop computers [33].

Mobile technology has been incorporated into health promotion programs targeting various health behaviors. Initiatives have targeted new parents [34], physical activity and nutrition [35-37], alcohol [38], suicide prevention [39], and mental health [40,41]. The use of smartphones offers specific benefits in terms of high user engagement [42], including the opportunity to deliver ecological momentary interventions [43]. These are interventions that occur as people participate in their daily lives and happen in real time [43]. As mobile users become increasingly savvy about app usage [44], their expectations grow, and it is important that apps developed for research purposes match the usability and sophistication that users expect from other "real-world" apps.

Developing mHealth interventions in multidisciplinary teams is a best practice approach recommended by many researchers [45-47]. It is important to design apps that are a good fit for user expectations and that make effective use of the devices on which they are deployed. Working with app development professionals early in the process can help to ensure that apps are well planned and executed [48]. This involvement can also identify trends in app development and user behavior, which may be incorporated into an app-based health intervention. In the case of Milk Man, we included push notifications, social connectivity, and gamification as engagement and motivational strategies.

Push Notifications

Push notifications are a means by which mobile apps can send information or alerts to users [49]. Compared with other notification methods, such as email, push notifications are immediate and quick to act upon; swiping the notification takes the users directly to the app, and even into the specific context referenced by the notification. Notifications remain in a list until they are acted upon or removed, meaning they can potentially act as triggers for later action. Use of push notifications means that the onus is not solely on a participant to remember to engage with the service; to some extent the service comes to them.

Social Connectivity

The use of technology for information gathering has changed markedly over the last 20 years. Increasingly, people want to interact with technology and use it to socially connect rather than simply passively receiving static information [50]. Many people are now socially connected throughout the day, over a number of platforms. Australians are enthusiastic users of social media, with approximately 68% of Internet users having at least one social media profile [51]. Breastfeeding research with fathers shows that peer support and peer connection is highly valued [14,16,21,23], and results from the FIFI study demonstrated that this approach can affect women's breastfeeding duration [12].

Socially connected mobile technology can encourage people to reach out to each other and build communities [52-55]. Encouraging results have been reported in studies of online social support communities in interventions across a broad spectrum of health areas, including weight management [52,56], physical activity [57], and social anxiety [58]. For example, a focus group study that investigated the feasibility of an app for overweight adults suggested that social support networks that create a virtual community could be the primary component in creating a successful healthy lifestyle app [52].

Gamification

Gamification is the practice of using game-like components to motivate and encourage people in non-game contexts, and it is becoming increasingly popular in health and fitness apps [59]. Gamification elements include badges, leaderboards, points, and challenges [60]. Evidence about the increasing use of gamified apps in health is emerging [47,61,62]. A review of physical activity and nutrition apps found that the use of gamification was widespread; however, behavior change theory was not widely incorporated and there was no industry standard for developers [62]. Several studies have noted the need for further investigation of the potential for gamified health apps to effect behavior change [47,61-63]. Australian mental health research with young men suggested that gamification may be of value in enhancing engagement and enjoyment with using technology [64].

Parent Infant Feeding Initiative

We developed the Milk Man app to be trialed as part of the Parent Infant Feeding Initiative (PIFI), which has been previously described [65] (ACTRN12614000605695). The PIFI study is a 4-armed RCT comprising 1 control group, 2 medium-intensity intervention groups, and 1 high-intensity intervention group. Participants are being recruited from antenatal classes at hospital sites in metropolitan Perth, Western Australia. The control group has access to the usual care provided by the hospital. One medium-intensity group receives a male-facilitated antenatal class, while the other has access to the Milk Man app. The high-intensity group has access to both the male facilitator-led antenatal class and the Milk Man app.

One of the largest intervention breastfeeding studies to target male partners, the PIFI study will be conducted between 2015 and 2017 and is expected to provide valuable insights into infant feeding outcomes. This paper focuses on the Milk Man app,

with particular emphasis on the formative research underpinning its design, development, and preliminary testing.

This research adds to the literature by describing the design and development of, to our knowledge, the first breastfeeding app targeted at men. The app uses carefully considered mobile strategies to engage men with an issue that is typically seen as the domain of women, and the results will add to the literature on mHealth and health promotion, particularly with respect to what works for targeting men with breastfeeding initiatives.

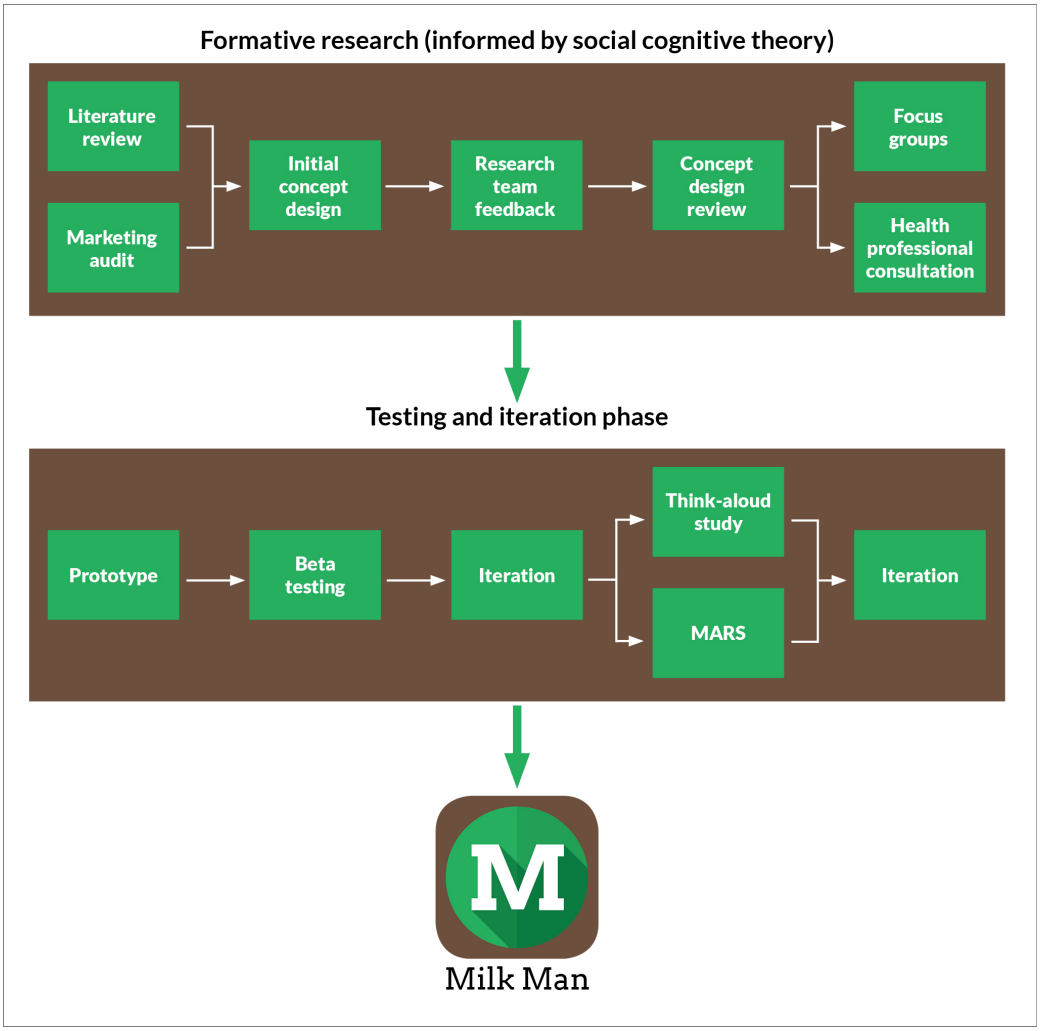
Methods

App Design

We developed the Milk Man app as a socially connected information and support resource for men. It is focused on breastfeeding and infant feeding, but includes broader information on topics including early parenting, being a supportive partner, and local service providers. It is based on evidence about the main factors affecting fathers' support of their breastfeeding partners and is informed by social cognitive theory (SCT). As part of the formative research process, we completed a marketing audit of current advertising campaigns investigating how health messages, products, and services were being designed for the target group. This information helped guide the design of the app. Breastfeeding interventions are often targeted at the mother, resulting in fathers reportedly feeling excluded from family support programs [14,16,19]. Milk Man was explicitly designed for, and targeted toward, fathers, and this was a key consideration in encouraging men to access and use the information.

Milk Man was informed by focus groups with men in the target group, in addition to consultation with health professionals. We refined it through a testing phase comprising beta testing and user testing with men in the target group. User testing involved participants completing a think-aloud walkthrough, as well as completing the Mobile Application Rating Scale (MARS) [66] (see Testing and Iteration sections below). Figure 1 illustrates the Milk Man development process.

Figure 1. Development process for Milk Man.



Theoretical Framework

SCT is a social learning model that operates at the interpersonal level, assuming an interaction between the social environment, the psychosocial determinants of behavior, and the individual [67,68]. In seeking to understand and predict human behavior, SCT can help to inform strategies for interventions to motivate and enable people to adopt healthier behaviors [69,70].

Reciprocal determinism is a key principle of SCT, describing the influence of both personal factors and the social environment

on a person's behavior. The factors that affect fathers' decisions about and capacity to support breastfeeding are broad and include a combination of environmental and personal influences. Two specific social environmental factors that have been identified in the literature for this target group are the sometimes complex issues related to public breastfeeding, and the role that health professionals can have [16]. SCT acknowledges the impact these influences can have rather than simply focusing on the individual. In recognition of this, SCT has been recommended in the literature as a useful framework for breastfeeding interventions that target fathers [22,71]. It was used as the basis for the FIFI study, particularly in designing the male-facilitated antenatal sessions, which considered the constructs of self-efficacy and observational learning. It also helped researchers to understand the potential interrelation of different factors, including the overestimation of parental capacity and the underestimation of potential problems with breastfeeding.

We based the design of the Milk Man app and its engagement model on SCT constructs, to address the key issues affecting men's support for their breastfeeding partners. The specific constructs of observational learning and goal setting were key components. In seeking to address self-efficacy, the app encourages problem solving between couples. Table 1 describes the theoretical framework underpinning the app and how the key engagement techniques used address the key factors identified in the literature.

Table 1. Milk Man engagement techniques mapped to social cognitive theory (SCT).

Key factors	SCT constructs	Engagement technique in Milk Man app
Social support		
Men feel they do not receive enough social support with pregnancy and early parenting.	Observational learning Goal setting Self-efficacy	Connected social support function via the guided "conversation" feature. App was specifically designed for, and targeted towards men. Gamification functions to encourage inclusion, engagement, and positive feedback.
Knowledge		
Men have gaps in knowledge around breastfeeding, pregnancy, and early parenthood.	Outcome expectations Goal setting Self-efficacy	Provision of information via the library, including practical solutions and support service contact details. Regular, age-relevant topics sent out as push notifications.
Empowerment		
Men report lack of recognition of paternal role and understanding of their supportive role.	Self-efficacy Self-regulation Outcome expectations	Focus on empowering men to understand their role through the library and the conversation. Provision of practical advice Encouragement to discuss issues with partner.
Barriers		
Men report specific barriers, including bonding postponement, public breastfeeding, and feeling left out.	Self-regulation Self-efficacy Observational learning Outcome expectations Goal setting	Forum for men to share information and an opportunity for discussion about solutions to barriers. Provision of information and strategies on public breastfeeding. Provision of information on specific barriers and solutions with the aim of establishing realistic outcome expectations.

Engagement Strategies

We specifically designed the app to be attractive and engaging to the target group. The app is contemporary, delivers important information in a fun and lighthearted manner, and contains quirky imagery throughout. Milk Man contains engagement strategies that aim to keep men interested in using the app. The main engagement strategies are the use of push notifications, social connectivity via a guided conversation, an information library, and gamification.

Push Notifications

The Milk Man app has new content being added in the form of conversation topics twice a week. Push notifications are used to alert users to new discussion topics.

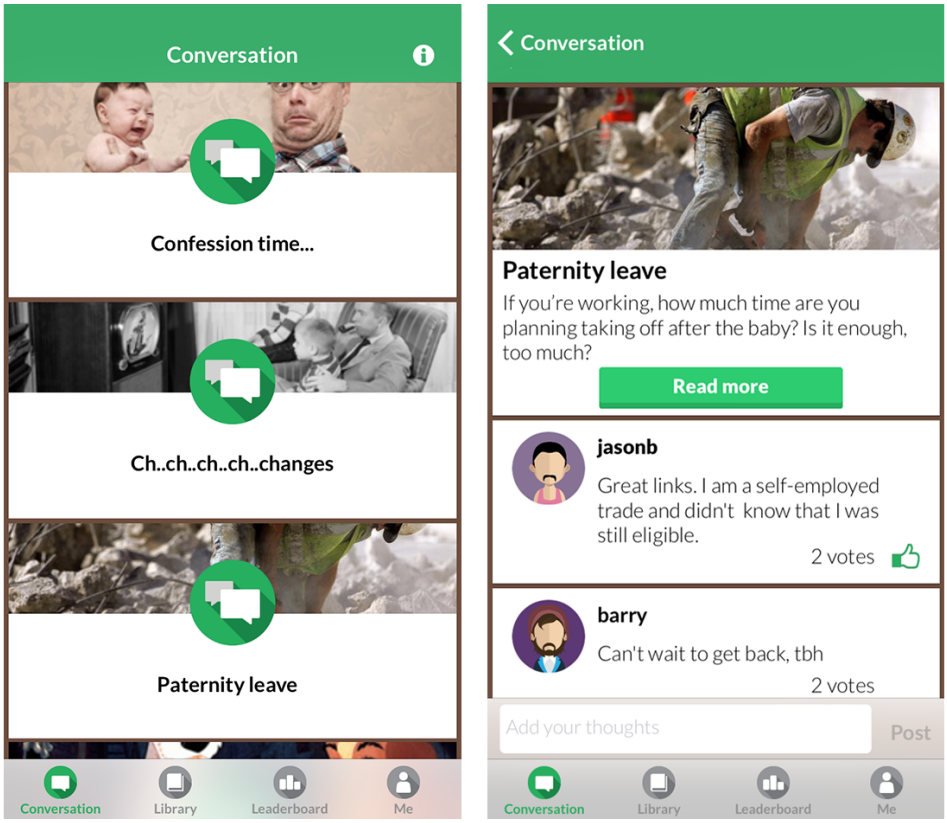
Social Connectivity Through Conversation

Milk Man aims to socially connect men by engaging them in a guided conversation. The conversation consists of a series of topics initiated by the app administration team twice a week. Participants receive a push notification alerting them to new topics and inviting them to participate in the conversation. On swiping the notification, they are taken directly to that conversation within the app. Topics are either posts or polls. A post, shown in Figure 2, consists of a question, usually with a link to a static information article in the library component of the app.

Users can add comments to the conversation, and "upvote" (that is, like or recommend) other users' comments. A poll is a multiple choice question, where users can choose an answer and view the aggregated responses of other users. Users are placed into conversation groups on the basis of the estimated

due date of their baby, enabling age-relevant information to be sent at appropriate times.

Figure 2. Milk Man conversation function.



Information Library

The app also contains a library of static, evidence-based information tailored specifically to fathers (see Figure 3). This includes information on preparing for fatherhood, breastfeeding and infant feeding, managing expectations, and how to seek support. The library uses the progressive disclosure technique [72], where information is sequenced so the initial information is concise, then progressively more detailed as the user requests further information. External links provide further information from service providers, including the Australian Breastfeeding Association [73] and the Raising Children Network [74]. We restricted the length of the articles to approximately 150 words to ensure content is succinct and minimal scrolling is required to see the whole article.

Gamification

The app uses leaderboards, badges, and points to encourage engagement with both the social conversation and the static library of information. Users are awarded points for commenting on posts, contributing to the conversation, voting on polls, receiving upvotes from other users, and reading library articles. Users can see their score and rank on the leaderboard. Figure 4 shows these features.

Figure 3. Milk Man library.

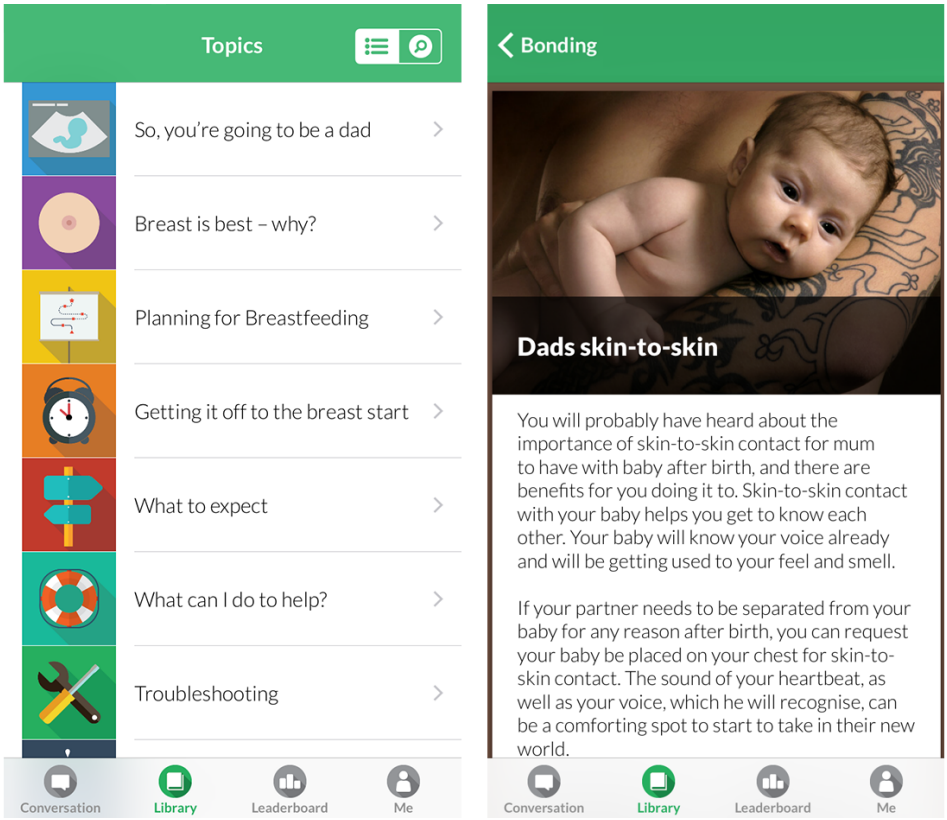
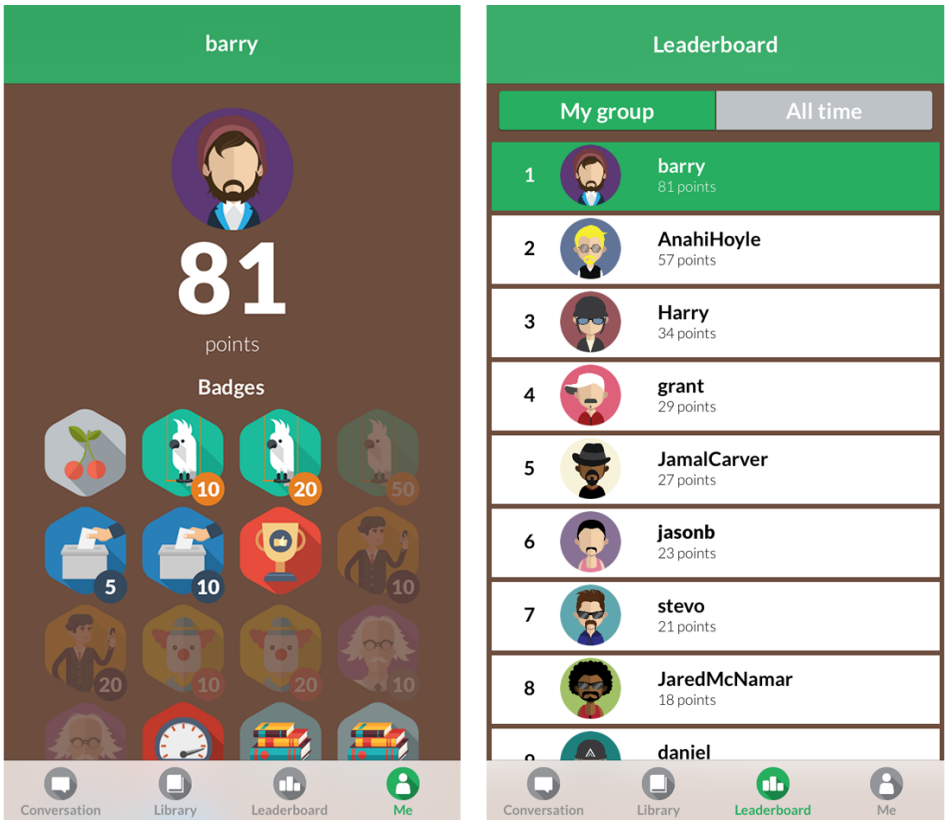


Figure 4. Gamification features used in Milk Man.



Formative Research to Inform Development of the App

Focus Groups With Target Group

Following internal review with the research team, we tested the initial app concept with members of the target group in a series of 3 focus groups. We recruited a purposive sample of men (n=18) through existing networks, including through the university staff and student body and a local playgroup. Participants were required either to be expecting a baby or to have a baby under the age of 6 months. The focus groups aimed to investigate the acceptability of the engagement strategies, provide guidance in the framing of the app, and ensure the proposed approach and content were appropriate. Participants were asked to complete a brief demographic survey before starting the session. The lead author recorded, transcribed, and reviewed the focus groups to maintain dependability [75].

Consulting Health Professionals

We held 2 separate consultative sessions with health professionals from 2 of the maternity hospital sites (1 public and 1 private) participating in the PIFI study. Before the session, we developed an outline of the library content to be included within the app, and this outline formed the basis for the discussion with stakeholders. We invited health professionals to comment on the proposed design, engagement strategies, and content of the app.

Testing and Iteration of the App Prototype Phase

App testing was divided into 2 phases: beta testing and user testing. The beta testing involved providing early versions of the app to experienced app testers, who examined it for errors, crashes, layout issues, software bugs, or other problems. Beta testing was not carried out by members of the target group, as we were not seeking design and functionality feedback at this stage. Rather, it was tested by 4 experienced software testers, as well as members of the research team. We incorporated feedback into successive iterations of the app.

The second phase of testing, user testing, involved obtaining feedback on the app's functionality, design, and usability. It was important that this phase of testing was carried out by members of the target group, as the objective was to gain an indication of the way in which the app was likely to be used and received by those for whom it was intended. Therefore, we invited participants to the testing phase if they were either expecting a baby or had a baby under the age of 6 months, and had previously expressed interest in the focus groups, but had not attended an earlier group. Once they had consented, we first asked participants to undertake a think-aloud walkthrough of the app, and then to complete the MARS [66,76]. We recruited 4 users to this testing phase. A previous study into think-aloud testing recommended that 4 to 5 test users is generally sufficient to identify up to 75% of usability issues, with the value of additional participants decreasing exponentially as the number increases [77].

Think-Aloud Walkthrough

Think-aloud walkthroughs are an industry standard approach in software development and a well-recognized way of testing mobile health apps [35,78-81]. In this study, after observing a researcher-led example using a different health app, participants were asked to spend a minimum of 10 minutes using Milk Man and to verbalize their thought processes as they navigated through the app. As the researcher wanted to observe the natural flow of app usage and observe organic navigation, the initial instruction was simply for users to "use and open the app as you would exploring any app for the first time."

As the participants explored the app independently, the researcher monitored a checklist of 10 tasks and marked each off as it was completed. At the completion of the walkthrough, we specifically asked users to complete any tasks on the checklist that they had not completed unprompted. In keeping with best practice in conducting think-aloud studies, the researcher remained quiet throughout the study, speaking only to remind the participant to keep talking aloud and to issue tasks at the end. We recorded and transcribed the think-aloud sessions.

Mobile Application Rating Scale

Released in December 2014, the MARS is a comprehensive questionnaire used for rating mobile health apps with reference to 5 key criteria. The first 4 *objective* quality subscales give a measure of *aesthetics*, *engagement*, *functionality*, and *information*, while the fifth criterion is a *subjective* quality subscale and seeks users' views on whether they would recommend the app, asks how often they would use it, and asks for an overall rating [66,76]. The MARS is scored by calculating the average of the 4 objective subscales. The MARS comprises 2 different versions, one for professionals, and a simplified version for app users. The app user version comprises 20 questions over the 5 criteria, with a final section asking 6 questions designed to describe the potential for impact on a user's knowledge, attitudes, and intention to change [76]. After completing the think-aloud study, users were asked to independently complete the app user version of this scale.

Results

Focus Groups With Target Group

A total of 18 men attended the 3 focus groups. Participants were aged between 30 and 43 years. Most were married (n=14), just under half were expecting a baby (n=8), and just over half had a new baby aged under 6 months (n=10).

All men owned either an iPhone or Android smartphone, and all said that they kept their phone close at hand and referred to it throughout the day. All participants had some third-party apps on their smartphone. Most participants were positive about the idea of apps for new fathers. Most of the comments about the use of push notifications were positive, although some mentioned that they should be used judiciously and the content should be relevant.

> *I think the lesson really is notification fatigue. You know some people like them, some people don't. I suppose if you got far too many you just become disinterested and that can actually be more dangerous than not getting a notification.* [Focus group 1]

There was a mixed response to the idea of a discussion forum for men to connect to each other. Some participants were very enthusiastic about the idea, while others stated they would not use it. Some of the reasons participants gave for ambivalence about a forum were not trusting the information, preferring to talk to people in real life, and that information on forums can be alarmist and cause unnecessary concern.

> *I don't know, I wouldn't talk to a stranger for starters on an app and then I mean you go, we go to barbeques and friends' house and their kids are ratbags or this and that and you can't tell your mate how to look after their kid, it's their kid. You don't know what they've been through the night before, you don't know what they've eaten the night before, so I wouldn't ask someone for advice on my child in that sense.* [Focus group 3]

> *We stopped trusting anything that wasn't from a doctor 'cause we got 50 opinions and my wife ended up freaking out.* [Focus group 1]

Some participants suggested that humor and a lighthearted tone would be appropriate, and that the app should be quick and easy to use.

> *For me lighthearted would be better. Even the best baby I think that first period is probably strap in and get through it kind of time. So if I have to read a textbook of really...dry text I'm probably not going to do it. But if it's something quick and easy that...tells me that what I'm seeing in front of me is correct [I'm more likely to use it].* [Focus group 1]

> *Push notifications can add that element to the humor.* [Focus group 2]

Reinforcing findings from the literature, men were also clear on wanting practical tips for helping their partner, with information ideally delivered in short, summarized formats, including bullets points and checklists. Access to more detailed information could be provided via links.

> *I want bullet points and if I want to read into it more I'll look into it more if I've got the time.* [Focus group 2]

> *Checklists, perhaps a list of [reasons why] my baby won't stop crying and then people could maybe leave suggestions. Doing an upvoting, downvoting vetted type system. Say "try this top answer, this worked really well" [or] "that didn't work, give me another thing on the list to try."* [Focus group 1]

Participants' experiences with mobile apps were varied, as were responses to the proposed engagement strategies. Some participants had experience sourcing and using apps for parenting and pregnancy, while others identified specific barriers to their use, including issues with trusting information and preferring face-to-face interaction. In general, fathers supported targeting fathers with such an approach, and the focus groups provided good insights into how to structure the app's engagement strategies.

Consulting Health Professionals

To provide input about the content and engagement strategies proposed for the app, 16 health professionals attended 1 of 2 sessions. All participants were hospital-based midwives working with new and expectant parents. Some had additional, specialist roles: they were lactation consultants or parent educators, or they were in charge of discharge and follow-up of patients. Some specialized in working with aboriginal families, with young families, or with families requiring complex care relating to issues with alcohol and other drugs, or mental health problems.

The health professionals were generally enthusiastic about the app, and in particular about having men as the focus of the intervention.

> *Knowing the success of the woman's breastfeeding experience is single-handedly influenced more by the support that [partners] give at home, than any other factor...makes [partners] feel like, "hey, I can do something to help."*

> *They want to help, but they don't know how they can help.*

The health professionals offered views that reinforced those from the focus groups, about keeping the tone of the app lighthearted, and ensuring the information provided was short and to the point.

> *Lighthearted and informative, because otherwise you'll lose them, and they won't come back if they're finding it too heavy and judgmental.*

> *Are you using dot form? Because I just find, they won't read a whole big [article]. You just need dot points [and] keywords.*

> *Pictures and dot points will work well.*

Health professionals also offered specific content recommendations, including websites and online videos they typically used with new parents. They further advised the need to include information about postnatal depression for fathers and to focus on the message that every breastfeeding is a success.

Testing and Iteration of App Prototype Phase

A total of 4 new or expectant fathers participated in the user testing phase. Of these 4 recruited participants, 3 had a baby aged under 6 months, while 1 was expecting a child. The age range was 34–44 years.

Think-Aloud Walkthrough

User testing via the think-aloud walkthrough identified 6 issues related to usability and functionality. Usability issues included text in the comments section being too small, a lack of clarity about how the points system worked, and the need for an important icon to be more prominent. In terms of functionality, 3 additional features were suggested: the ability for users to post their own questions, the inclusion of a tutorial or walkthrough to explain the different sections of the app, and the ability to later change the avatar they had selected on creating a user profile.

Most participants completed the 10 tasks on the walkthrough checklist while independently using the app, without needing to be prompted. In each case, they completed all of the remaining items when prompted.

Mobile Application Rating Scale

We averaged the MARS scores from each user list them in Table 2. All 4 participants said they would recommend the app, and they all gave the app a 4- or 5-star rating.

Table 2. Average (out of 5) Mobile Application Rating Scale (MARS) scores for each category applied to the Milk Man breastfeeding app.

MARS criterion	Average score
Aesthetics	4.3
Engagement	3.8
Functionality	4.6
Information	4.5
Total average score	4.3

Discussion

Developing and Refining Milk Man

Formative research was a critical component of the development process used for the Milk Man app. Guided by the existing literature, and theoretically underpinned by the SCT, the app content and functionality were refined and focused through feedback and input from clinical health professionals, members of the target group, and a multidisciplinary team of professionals. These professionals included breastfeeding researchers, health promotion professionals, nutritionists, and a midwife, as well as an app designer and developer. Qualitative data from the formative evaluative phase provided insight into the use of mobile technology by members of the target group and into what engagement strategies might be most effective. While this was not intended to be an exhaustive qualitative study to thematic saturation, there were many overlapping themes and participants provided rich insight to help guide the app development.

The testing phase identified 6 issues, 5 of which we addressed before starting the PIFI trial. The one identified issue that we did not act on was the suggestion that users could post their own conversation topics. We deemed this to be outside the scope of this research and a potential risk, in that topics could be poorly informed and contain inaccurate or misleading information. We added a brief tutorial (usually known as an onboarding exercise), to be displayed to users on first launching the app. This addressed several of the identified issues, including a description of the points system, an explanation of how the app worked, and an explanation of how users would be assigned to a group.

MARS scores were high, indicating good user acceptability, usability, and functionality. While still high, the engagement score was slightly lower. This appeared to relate to participants' stated need for further instructions, explanations, and the ability to change avatars to better customize their user account, all issues that we addressed in the next iteration of the app.

Next Steps for Milk Man

We have developed a comprehensive evaluation plan to measure the acceptability and effectiveness of the Milk Man app in the PIFI RCT. We will collect data through a mixed methods approach, including a customized analytics framework built into the app and a self-report questionnaire, which users will complete when their baby is 6 weeks old, and again at 26 weeks.

Evaluating adaptive technological interventions such as this requires a comprehensive approach, and we based the evaluation framework for this research on the one proposed by O'Grady et al [82]. This framework includes indicators for app users, content analysis, technology, computer-mediated interaction (user interaction with the interface), and broader health system integration.

While the use of mobile technology in public health interventions has grown significantly, there are still too few high-quality, adequately powered RCTs evaluating the use of such apps [83,84]. This large RCT will add to the evidence about the efficacy of mobile technology in delivering health interventions. The robust evaluation design will have broader relevance to public health interventions looking to use mobile technology to reach target groups.

Limitations

This study sought to include the views of members of the target group in the app design and development through focus groups. Participants in the focus groups were aged between 30 and 43 years, meaning that younger fathers were not represented in this sample. This was due to the purposive sampling method used. However, this research builds on the aforementioned FIFI study, in which both younger and older fathers were consulted.

Although we recruited only 4 participants for the testing phase, this number has been previously shown to be effective in identifying most usability issues [77], and indeed participants' reported issues overlapped significantly. While the MARS has been found to provide a reliable indicator of app quality when used by trained raters, the reliability of the app user version is being evaluated [66]. As such and because of the small number of users rating the app, these results should be interpreted with caution.

Technology changes quickly. There is a balance to be struck between developing health intervention apps in a thorough, methodical fashion and moving quickly to minimize the risks associated with a changing technological environment. To minimize these risks, we proceeded to the RCT without a pilot study. A larger pilot study of the app, before starting the PIFI

study, would have been of value in providing further insight into the way in which men would use the app in a real setting. This may be particularly true of the more interactive components of the app, such as the conversation and the leaderboard; observing men engaging with these features may have further assisted refinement. However, we will be able to monitor this throughout and make those recommendations at the trial's conclusion.

Conclusion

Milk Man is a theoretically grounded app that provides information and support for the antenatal and postnatal periods and aims to socially connect fathers around a central theme of breastfeeding. We anticipate that providing a platform for men to discuss, share, and support each other through the breastfeeding journey will positively affect the support they offer their partners.

To our knowledge, Milk Man is the first breastfeeding app developed specifically for men. It uses innovative strategies to encourage user engagement. The development of Milk Man has involved stages of formative research, testing, and iteration. The process of design, development, and testing described here follows a best practice approach to app development, including being developed by a multidisciplinary team, being based on behavior change theory, and a having a design process centered on the user.

The comprehensive evaluation plan includes indicators for the app's engagement strategies, as well as psychosocial and health outcomes up to 6 months after the birth of a child. This will provide valuable insights into what works for reaching the target group, and will ensure that the findings are transferable and that the data will be broadly relevant to future mobile health interventions. We expect results from the PIFI study in 2017.

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Conflicts of Interest

None declared.

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Abbreviations

FIFI: Fathers Infant Feeding Initiative
MARS: Mobile Application Rating Scale
PIFI: Parent Infant Feeding Initiative
RCT: randomized controlled trial
SCT: social cognitive theory

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Original Paper

Enhancing Pharmacy Student Learning and Perceptions of Medical Apps

Jennifer Rodis[1], PharmD; Timothy Dy Aungst[2], PharmD; Nicole V Brown[3], MS; Yan Cui[4], PharmD; Leonard Tam[2], PharmD

[1]The Ohio State University College of Pharmacy, Division of Pharmacy Practice and Science, Columbus, OH, United States

[2]MCPHS, School of Pharmacy, Worcester, MA, United States

[3]The Ohio State University, Center for Biostatistics, Columbus, OH, United States

[4]The Ohio State University College of Pharmacy, Columbus, OH, United States

Corresponding Author:
Jennifer Rodis, PharmD
The Ohio State University College of Pharmacy
Division of Pharmacy Practice and Science
500 W. 12th Ave
Columbus, OH, 43210
United States
Phone: 1 614 247 8391
Fax: 1 614 292 1335
Email: rodis.2@osu.edu

Abstract

Background: The use of mobile apps in health care is growing. Current and future practitioners must be equipped with the skills to navigate and utilize apps in patient care, yet few strategies exist for training health care professional students on the usage of apps.

Objective: To characterize first-year pharmacy student use of medical apps, evaluate first-year pharmacy student's perception of skills in finding, evaluating, and using medical apps before and after a focused learning experience, and assess student satisfaction and areas for improvement regarding the learning experience.

Methods: Students listened to a recorded, Web-based lecture on finding, evaluating, and using mobile apps in patient care. A 2-hour, interactive workshop was conducted during which students were led by an instructor through a discussion on strategies for finding and using apps in health care. The students practiced evaluating 6 different health care–related apps. Surveys were conducted before and after the focused learning experience to assess students' perceptions of medical apps and current use and perspectives on satisfaction with the learning experience and role of technology in health care.

Results: This educational intervention is the first described formal, interactive method to educate student pharmacists on medical apps. With a 99% response rate, surveys conducted before and after the learning experience displayed perceived improvement in student skills related to finding (52/119, 44% before vs 114/120, 95% after), evaluating (18/119, 15% before vs 112/120, 93% after), and using medical apps in patient care (31/119, 26% before vs 108/120, 90% after) and the health sciences classroom (38/119, 32% before vs 104/120, 87% after). Students described satisfaction with the educational experience and agreed that it should be repeated in subsequent years (89/120, 74% agreed or strongly agreed). Most students surveyed possessed portable electronic devices (107/119, 90% mobile phone) and agreed with the concept of medical apps being an important part of the health care profession in the future (112/119, 94% before and 115/120, 96% after).

Conclusions: Student pharmacists recognize the key role technology plays in the future of health care. A medical apps workshop was successful in improving student pharmacists' perceptions of ability to find, evaluate, and use medical apps.

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KEYWORDS

mobile applications; pharmacy; students; health care

Introduction

With the worldwide popularity of mobile devices (eg, mobile phones, tablet computers), mobile apps are increasingly being used by health care professionals in a variety of settings. A mobile device is defined as "a portable, wireless computing device that is small enough to be used while held in the hand" [1]. In the health care field, it is estimated that there will be 500 million smartphone users worldwide with mobile health apps by 2015, and the global market for these apps may reach US $26 billion by 2017 [2]. There are more than 43,000 health care, fitness, and medical apps available in English on iTunes [3]. As mobile technology continues to gain popularity, health care practitioners, students, and residents are gravitating toward the utilization of mobile devices to assist in their clinical duties and education [4-9].

Clinicians have access to mobile medical apps that serve as drug references, clinical calculators, disease references, and clinical decision-processing aides [10,11]. Pharmacists have also integrated mobile devices as a means to help process medical orders in the hospital, access clinical references, and increase communication with providers in their practices and professional duties [12-14]. Although medical apps are helping advance the field of health care in this digital era, there are certain pitfalls being noted by the health care and academic communities related to the quality of the apps and evidence of health information provided in them [15-17]. One of the biggest issues is the reliability and accuracy of information found within the plethora of medical apps available. Several studies have identified these concerns, with issues ranging from lack of medical evidence, nondisclosure of authorship, design flaws, and inaccurate information [18-21].

The Food and Drug Administration (FDA) has recently released guidelines on which subset of medical apps it will review and regulate [22]. Whereas the safety of such apps is being ensured by FDA standards, apps that record life events, extract medical content, serve as clinical or drug references, or facilitate the communication between clinicians or health centers with patients will not be regulated by the FDA [17]. Given the limited scope of FDA in monitoring medical apps, relevance and reliability of these apps will need to be determined by the users. As health care professionals, pharmacists should have the adequate background and understanding of these apps to critique the information provided, to be able to recommend to patients or colleagues, and to use them effectively when providing care.

Future health care practitioners will likely be the generation to formally adopt mobile technology into their workflow and clinical practice. Studies have identified that mobile devices and medical apps are increasingly being incorporated into formal medical education [23-25]. However, strategies on educating current and future pharmacists to use apps effectively have not been reported. The objectives of this study were to characterize first-year pharmacy student use of medical apps, evaluate first-year pharmacy student's perception of skills in finding, evaluating, and using medical apps before and after a focused learning experience, and assess student satisfaction and areas for improvement regarding the learning experience.

Methods

Description of Learning Experience

Faculty from The Ohio State University College of Pharmacy (OSU COP) and Massachusetts College of Pharmacy and Health Sciences (MCPHS) University School of Pharmacy collaborated to create a novel learning experience for pharmacy students that focused on finding, evaluating, and using medical apps. The project was approved as exempt research by The Ohio State University Institutional Review Board. At OSU COP, foundational concepts related to drug information, including literature assessment, are taught in the spring semester of the PharmD curriculum as a distinct module that is part of an introductory pharmacy practice course series. During this module, students are engaged with didactic, workshop, and project-based experiences focused on finding, evaluating, and using drug information in patient care. This medical app educational experience was integrated into this course. This two-part learning experience involved a prerecorded, Web-based lecture that students were required to view before arriving for a 2-hour, small group workshop of approximately 30 students to apply concepts learned in the lecture. Available for 1 week before the workshop, the 38-minute lecture was created by the faculty member from MCPHS, video recorded via QuickTime, and uploaded onto a private view YouTube profile made available to OSU COP students. The lecture content was based on the role of mobile medical apps in clinical practice, issues and opportunities with utilization of medical apps, and how to review and assess medical apps. The lecture demonstrated to students how to evaluate mobile medical apps with several examples provided. In addition to the lecture, a tool for evaluating medical apps was shared with students; they were required to bring a copy of this tool with them to the workshop. This tool was developed by one of the coinvestigators and previously published incorporating previous strategies published [26,27].

Prior to the workshop, students were sent a list of medical apps that could be used free of charge and were available for download to portable electronic devices with iOS or Android operating systems, such as mobile phones or tablets. Students were asked to download these apps to a device, if available, before the workshop. Medical apps were selected by faculty and then reviewed before the start of the workshop. Identification of apps was conducted via previously identified means [26], with an emphasis on apps related to pharmacy practice, drug information, medical calculators, and general clinical knowledge. Apps were reviewed for both positive and negative qualities to spur discussion among students regarding evaluation techniques during the course of the workshop. The medical apps selected for inclusion in the workshop are detailed in Table 1.

Table 1. Mobile apps used in class activity.

Mobile app	Operating system
Medscape	iOS and Android
BodyXQ Heart	iOS and Android
Glucagon	iOS
Psych Drugs	iOS and Android
Cardiology Tool by Epocrates	iOS
Managing Dabigatran	iOS and Android

When students arrived to class, a discussion was led by the instructor to review key concepts covered in the previously posted Web-based lecture, including how to use the medical app evaluation tool. The discussion also involved a facilitated conversation about where students find apps and students' experience with apps that had been useful or not useful. Students were split into groups of 4 to 5 students each (6 groups in total per workshop) to evaluate up to 6 medical apps. Each group presented their experience using the evaluation tool to the class and discussed what the individual groups had found with a focus on challenges in evaluating medical apps as well as how to determine what apps are useful in practice.

Evaluation of Learning Experience

Metrics were collected from YouTube Analytics on the number of views and visits received before the start of the workshop. To evaluate the effect of these medical apps on learning experience, prospective surveys were conducted before and after the involvement of first-year pharmacy students in the learning experience (see Multimedia Appendices 1 and). The surveys were created by the faculty collaborators on the project from OSU COP and MCPHS to assess changes in students' perceptions regarding how to find, evaluate, and use medical apps in pharmacy. Descriptive questions were asked to characterize the use of portable electronic devices and medical and nonmedical apps by this student population. The first survey included 27 questions involving 5-point Likert scale format (strongly agree to strongly disagree) for perceptions on student confidence with finding, evaluating, and using medical apps. Multiple choice, check all that apply, and open-ended questions were also included to gather information regarding app and device use. The second survey included 18 questions involving the same 5-point Likert scale format questions as well as many of the same multiple choice and check-all-that-apply questions for comparison with the first survey's responses. Demographic data collection about device ownership and population characteristics was not repeated. The second survey additionally asked about satisfaction with the learning experience. Deidentified data were entered into an Excel spreadsheet, then analyzed descriptively in aggregate with summary statistics, including 95% confidence intervals for proportions where appropriate, which were generated in SAS v9.2 (SAS Institute, Cary, NC).

Both surveys were conducted during the workshop as paper surveys. The first survey was conducted on the first day of workshop for the semester. The second survey was administered during the workshop 2 weeks after the medical apps workshop experience.

Results

Pharmacy Student Use of Mobile Applications

The first-year class includes a total of 120 students. There were 96 visits to the YouTube video before the start of the workshop. From the first-year pharmacy class of 120 students, 119 students completed the first survey whereas 120 students completed the second survey. Differences in response total were due to 1 student being absent from class the day the first survey was conducted. Demographics of students gathered are shown in Table 2 and are typical of a first-year PharmD class across the United States. Of 119 students, 107 (90%) own a mobile phone and 86 (72%) own a portable electronic device.

Table 2. Demographics (N=119).

Characteristic		n (%)
Sex, female		75 (63)
Age, years		
	18-25	100 (85)
	25-30	15 (13)
	31-35	2 (2)
	36-40	1 (1)
Race		
	Caucasian	90 (77)
	African American or black	4 (3)
	Asian	21 (18)
	Other	2 (2)
Device ownership		114 (96)

On the basis of the results of the first survey, most students learned about apps via word of mouth, including obtaining information from classmates (96/119, 81%), social media such as Facebook, Twitter, and blogs (58/119, 49%), pharmacy staff at work (44/119, 37%), and family (44/119, 37%; Table 3).

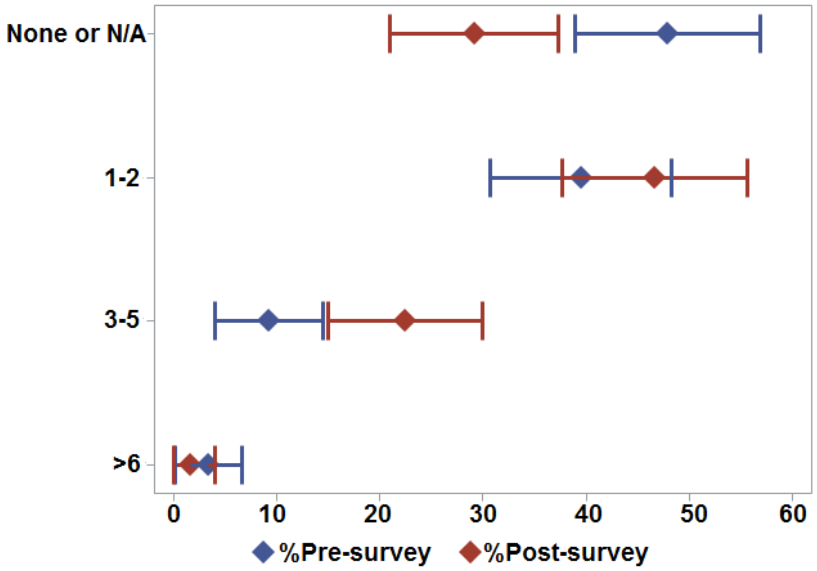
Table 3. Responses regarding where students learn about new apps, before and after the learning experience.

Source	Before (n=119)			After (n=120)		
	n	%	95% CI	n	%	95% CI
Family	44	37	28-46	22	18	11-25
Friends or classmates in pharmacy school	96	81	74-88	100	83	77-90
Friends or classmates from other health professions schools	27	23	15-30	33	27	20-35
Medical or pharmacy Staff where I work	44	37	28-46	57	47	39-56
Facebook	38	32	24-40	19	16	9-22
Twitter	11	9	4-14	2	2	0-4
Blogs	9	8	3-12	6	5	1-9
News	26	22	14-29	14	12	6-17
Professional organizations	11	9	4-14	8	7	2-11
Other	4	3	0-7	12	10	5-15
None of the above or N/A[a]	7	6	2-10	6	5	1-9

[a]N/A: not applicable.

In addition, most students reported regularly using 0 to 2 medical or pharmacy-related apps and approximately 55% (65/119) of students indicated currently having a drug information app installed on a portable electronic device (Figure 1).

Figure 1. Medical apps owned per student. Proportions (diamonds) and 95% confidence intervals (horizontal lines) for the surveys conducted before (pre-survey) and after (post-survey) the learning experience. N/A: not applicable.



Impact of Learning Experience on Student Perceptions of Mobile Applications

Before the workshop, most students indicated that medical or pharmacy-related apps are beneficial to pharmacy practice (98/119, 82%) and that mobile technology will influence pharmacy practice in the future (112/119, 94%). However, less than 44% of students agreed or strongly agreed that they knew how to find (52/119, 44%), evaluate (18/119, 15%), or use medical or pharmacy-related apps (31/119, 26%; Figure 2).

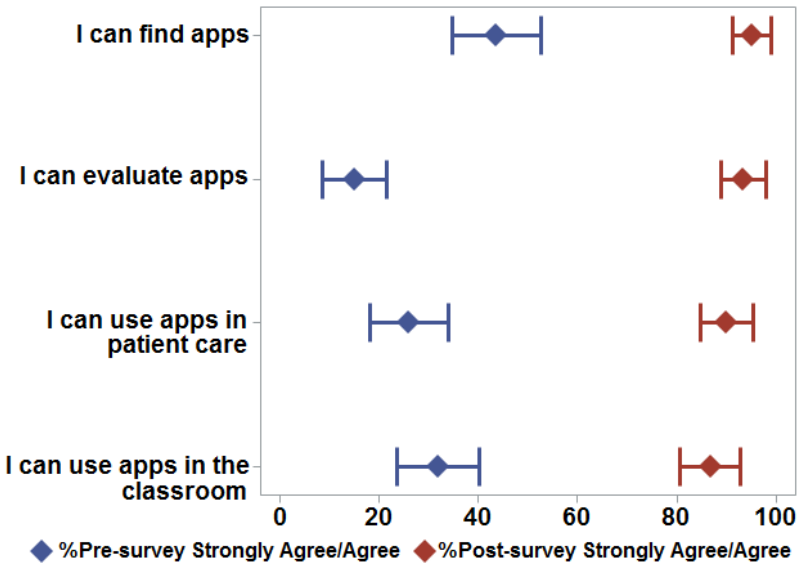
The students cited lack of knowledge of apps and inability to recognize when it was appropriate to use a mobile device in practice as the two main barriers to using mobile devices in pharmacy practice (Table 4).

Table 4. Responses regarding student-identified barriers to using apps, before and after the learning experience.

Barriers to using apps	Before (n=119)			After (n=120)		
	n	%	95% CI	n	%	95% CI
Lack of knowledge of apps	87	73	65-81	69	58	49-66
Technical difficulty	37	31	23-39	37	31	23-39
Purchasing a device	35	29	21-38	49	41	32-50
Recognizing when it's appropriate to use one	66	55	47-64	66	55	46-64

The second survey's responses indicated changes in students' perceptions in a variety of areas after participating in the medical apps learning experience (Figure 2). After the workshop, more than 90% of students agreed or strongly agreed that they knew how to find (114/120, 95%), evaluate (112/120, 93%), and use medical apps (108/120, 90%), compared with 43% before the workshop (Figure 2). Most students also reported increased usage of apps than on the first survey with up to 5 medical or pharmacy-related apps regularly used (Figure 1). Eighty percent of students (96/120) indicated that a drug information app was currently installed on one of their mobile devices. The source of information about new apps also changed after the workshop, with students indicating that they relied more on colleagues than social media and family to learn about new apps (Table 3). Perceptions on benefits and barriers to using mobile devices in pharmacy changed minimally, with the percentage of students agreeing or strongly agreeing that apps benefit pharmacy practice and that mobile technology will influence pharmacy practice increasing from 95% (113/119) to 96% (115/120). Lack of knowledge was indicated as a barrier less often in the second survey compared with the first survey (Table 4). Also, students' perceptions related to the cost of a medical or pharmacy-related app did not differ between first and second survey data. Most students were willing to pay less than US $2.99 for a medical or pharmacy-related app. Overall, most students found the medical apps presentation and the activities to be useful (at least 70% agreed or strongly agreed, 84/120) and that they would suggest offering the activity in the class next year (74% agreed or strongly agreed, 89/120).

Figure 2. Student assessment of evaluation technique. Proportions (diamonds) and 95% confidence intervals (horizontal lines) for the surveys conducted before (pre-survey) and after (post-survey) the learning experience.



Discussion

This educational intervention is the first described formal, interactive method to educate pharmacy students on medical apps. Comparative surveys conducted before and after the experience display a perceived improvement in student skills related to finding, evaluating, and using medical apps. Students described satisfaction with the educational experience and agreed that this experience should be repeated in subsequent years. Most students surveyed possessed portable electronic devices, used apps regularly, and agreed with the concept of medical apps being an important part of the health care profession in the future.

Current literature reveals that medical trainees in a variety of practice environments share similar trends and perceptions of medical apps. A study of US urology trainees found that 77% reported downloading apps with 30.6% also paying for them; the mean number of apps downloaded was 4 (range 1-12). Approximately 44% of trainees indicated apps for mobile phones as being very useful in clinical practice [28]. Our pharmacy students reported similar app-downloading habits, with a much higher percentage believing apps are integral to the practice. Methods to evaluate apps have been published, including the tool used in this project [26,27,29]. No models for educating health care professionals on finding, evaluating, or using apps have been described. Greater emphasis on educating future health care practitioners in the classroom on the appropriate use of mobile technology has been suggested [30].

Although our study demonstrated that students felt more comfortable with evaluating mobile medical apps, our results indicated that they still felt they would benefit from greater knowledge on when it is appropriate to use the technology in practice. Although this was not a focus of our study, our results suggest possible benefit from addressing the topic of e-professionalism and the integration of mobile devices into practice in pharmacy and possibly other health sciences curricula.

Limitations of this project relate to the narrow scope of the educational intervention. This intervention occurred in one course at one pharmacy school with first-year pharmacy students who have not yet experienced patient care at the level of more advanced students and may not be ready to apply the experience to real-life medication management in practice. Although the faculty attempted to choose a variety of medical apps to evaluate in one workshop session, we were able to accommodate up to 6 total apps. A greater variety may have allowed for a more in-depth discussion through application to core concepts. Approximately 80% of the class viewed the preparatory Web-based training module before the workshop, though it cannot be determined if each video view was conducted by each student alone or in groups. Despite this, data were analyzed in aggregate and showed overall improved perceptions by the majority of the class. Another limitation to considering the effect of this experience is that faculty evaluated student perception of skills with no formal assessment of student abilities. Data on students' general use of digital technology, including social media, were evaluated as demographic information to describe the population and not assessed in the second survey; thus, investigators are unable to identify any effects this learning experience may have had on this digital technology usage. Additionally, unique identifiers were not collected to match each student's responses for the first and second data collection. Consequently, no formal hypothesis testing for the changes before and after the learning experience could be performed and analyses of the data were limited to descriptive summaries.

Medical apps will be an inevitable component of health care in the 21st century. Pharmacy and other health care professionals must be equipped with the skills to navigate this new open-access world to provide safe and effective recommendations and care of patients. An important element of the portable technology world is medical apps. This paper

describes a model for engaging pharmacy students in an active learning experience in finding, evaluating, and using medical apps. This model is transferable to other colleges of pharmacy as well as other health care professional training programs aimed at both current and future practitioners.

Conflicts of Interest

TDA helped author the tool used to evaluate mobile medical apps that was previously published, and he was also a previous editor for iMedicalApps.com where he reviewed and assessed mobile medical apps.

Multimedia Appendix 1

Pre-Survey.

[PDF File (Adobe PDF File), 78KB - mhealth_v4i2e55_app1.pdf]

Multimedia Appendix 2

Post-Survey.

[PDF File (Adobe PDF File), 74KB - mhealth_v4i2e55_app2.pdf]

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Abbreviations

FDA: Food and Drug Administration
MCPHS: Massachusetts College of Pharmacy and Health Sciences
OSU COP: The Ohio State University College of Pharmacy

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Original Paper

Development and Validation of the User Version of the Mobile Application Rating Scale (uMARS)

Stoyan R Stoyanov[1,2], MRes(Psych); Leanne Hides[1,2], PhD(Clin); David J Kavanagh[1,2], PhD; Hollie Wilson[1,2], PhD

[1]Centre for Children's Health Research, Institute of Health & Biomedical Innovation, School of Psychology and Counselling, Queensland University of Technology (QUT), Brisbane, QLD, Australia

[2]The Young and Well Cooperative Research Centre (Young and Well CRC), Abbotsford, VIC, Australia

Corresponding Author:
Leanne Hides, PhD(Clin)
Centre for Children's Health Research, Institute of Health & Biomedical Innovation
School of Psychology and Counselling
Queensland University of Technology (QUT)
CCHR, QUT
62 Graham Street
Brisbane, QLD, 4101
Australia
Phone: 61 730697592
Fax: 61 730697119
Email: leanne.hides@qut.edu.au

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Abstract

Background: The Mobile Application Rating Scale (MARS) provides a reliable method to assess the quality of mobile health (mHealth) apps. However, training and expertise in mHealth and the relevant health field is required to administer it.

Objective: This study describes the development and reliability testing of an end-user version of the MARS (uMARS).

Methods: The MARS was simplified and piloted with 13 young people to create the uMARS. The internal consistency and test-retest reliability of the uMARS was then examined in a second sample of 164 young people participating in a randomized controlled trial of a mHealth app. App ratings were collected using the uMARS at 1-, 3,- and 6-month follow up.

Results: The uMARS had excellent internal consistency (alpha = .90), with high individual alphas for all subscales. The total score and subscales had good test-retest reliability over both 1-2 months and 3 months.

Conclusions: The uMARS is a simple tool that can be reliably used by end-users to assess the quality of mHealth apps.

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KEYWORDS

MARS; mHealth; eHealth; app evaluation; end user; app trial; mhealth trial; user testing; mobile application; app rating; reliability; mobile health; well being; mental health; smartphone; cellphone; telemedicine; ehealth; emental health; e-therapy; Internet; online; cognitive behavioral therapy; anxiety; anxiety disorders; depression; depressive disorder; Australia; research translation; evidence-informed; mHealth implementation; mHealth evaluation; randomized controlled trial; RCT

Introduction

Mobile health (mHealth) apps have the potential to provide around-the-clock access to evidence-based health information, education, and treatment to end users on a global scale. There are currently more than 165,000 mHealth apps (free and paid) publicly available [1], yet the accuracy of the health information contained in these apps is not scrutinized by regulatory bodies [2], which could compromise user health and safety [3-5]. Concerns about the quality, efficacy, reliability, and security of mHealth apps are also often raised. While meta-analytic studies have demonstrated the efficacy of mHealth apps targeting

physical activity and weight loss [6,7], the evidence base for other types of mHealth apps is poor at best [8-10].

In response to these issues, we developed the Mobile App Rating Scale (MARS) to provide researchers, professionals, and clinicians with a brief tool for classifying and assessing the quality of mHealth apps [11]. The 23-item MARS contains 4 objective quality subscales—engagement, functionality, aesthetics, and information quality—and a subjective quality rating. The MARS has demonstrated high levels of interrater reliability for evaluating the quality of mHealth apps on well-being [11] and mindfulness [9]. However, training and expertise in mHealth and the relevant health field is required to administer it. This paper describes the development and pilot testing of a simpler, *end user* version of the MARS (uMARS) and provides preliminary evidence for its internal consistency and test-retest reliability.

Methods

Study 1: Development and Pilot Testing of the uMARS

The original MARS was simplified through the following process. The professional version was first reviewed by 2 researchers to remove complex terminology from its items and response scales. Three items requiring professional expertise, pertaining to evidence base, app goals, and accuracy of app description, were removed. Readability of the MARS and the draft uMARS was then determined using the Flesch Reading Ease test [12,13], which has a score range of 0-100, with higher scores indicating easier readability. This measure also provides the estimated US school grade required for reading comprehension.

The draft uMARS was then pilot-tested with 13 young people, to ensure they understood the item content and response scales. The measure was embedded in prototype testing sessions of 2 mHealth apps: *Ray's Night Out* [14] and *Music eScape* [15]. *Ray's Night Out* uses a harm-minimization approach to increase young people's alcohol knowledge and awareness of their drinking limits; *Music eScape* teaches young people how to identify and manage affect using music. Both are available on the iOS Apple app store.

Eligible participants were Australian residents aged 16 to 25 years, who had access to an iPhone 4 or later model. The *Ray's Night Out* group comprised 1 male and 8 females with a mean age of 20.7 years (SD 1.6). The *Music eScape* group comprised 3 males and 1 female, with a mean age of 21.5 years (SD 1.9). After testing the apps and rating them with the uMARS scale, participants were asked the question "Do you have any comments or suggestions about the uMARS rating scale?" to identify any unclear or difficult items.

Study 2: Testing the uMARS Internal Consistency and Test-Retest Reliability

The uMARS (Multimedia Appendix 1) provides a 20-item measure that includes 4 objective quality subscales—engagement, functionality, aesthetics, and information quality—and 1 subjective quality subscale.

The reliability of the uMARS was evaluated as part of a randomized controlled trial (RCT), testing the efficacy and quality of *Music eScape*. The RCT sample comprised 164 Australians aged 19.8 years on average (SD 2.51); 34 males. The highest level of education completed by 59.8% of the sample was secondary school, and 24.4% had completed a bachelor's degree or higher. Most participants (57.9%) were students and 35.4% had full-time, part-time, or casual employment.

Participants were randomly allocated via a Web-based research management tool developed at the Queensland University of Technology to receive immediate or 1-month delayed access to the *Music eScape* app. Young people were asked to use the app as much as they liked over a month, using their own iPhones. The current iOS version at the time of the trial was iOS8. Participants received weekly text messages reminding them to do so. App ratings were collected using the uMARS at 1-, 3-, and 6-month follow-ups in the immediate access group. In the delayed access group, uMARS ratings were collected at 2-, 3-, and 6-month follow-ups (ie, after 1, 2, and 5 months of app access). At each assessment point, participants were asked if they had used the app since the last assessment, and only those who reported some use were included in analyses.

Data Analysis

The internal consistencies of the uMARS subscales and total score were calculated using Cronbach's alpha. For the purpose of analysis, the "N/A" answer option for items 13-16 of the *information* subscale was recoded as "system missing," as this option represents a qualitatively different response.

Test-retest reliabilities were calculated for the subscales and total scores of the uMARS after 1 month of app use and at 3 months post baseline (ie, a test-retest period of 1-2 months), and over 3 months (ie, between assessments at 3 and 6 months post baseline). Interclass correlation coefficients (ICCs) [16-18] were used, as they provide weighted values of rater agreement and assess proximity rather than equality of ratings. To calculate the ICCs, a random-effects average measures model with absolute agreement was utilized [16]. Data were analyzed with SPSS version 23 (SPSS Inc, Armonk, NY, USA).

Results

Study 1: Readability

Results of the Flesch-Kincaid readability tests are in Table 1. Scores indicated that the uMARS was written in plain English and that its required reading level was approximately grade 8.

Pilot Participant Feedback

No suggestions for further scale improvement were made. Seven of the 13 participants who pilot-tested the scale left the comments or suggestions item blank, 4 wrote "no," and 1 wrote "Well done. Good questions. Well explained." Another wrote "I thought it was shorter/there is a brief or revised version of it?"

Study 2: uMARS Internal Consistency

A total of 152 of the 164 (92%) participants completed the survey after 1 month of app use. Of these, 19 indicated they never used the app, and were excluded from analyses. For the remaining 133 participants, the total uMARS score had excellent internal consistency (Cronbach alpha = .90). Internal consistencies of its subscales were also very high (engagement alpha = .80; functionality alpha = .70; aesthetics alpha = .71; information alpha = .78; and satisfaction alpha = .78).

uMARS Test-Retest Reliability

Test-retest reliabilities are presented in Table 2. A total of 113 participants completed the scale after 1 month of app use and at 3 months post baseline (ie, a test-retest period of 1-2 months), and 74 completed both the 3- and 6-month surveys (giving a 3-month test-retest period). All included participants had used the app at least once since the previous survey. The uMARS total score demonstrated *good* [16] levels of ICC of .66 and .70 over 1- to 2-month and 3-month periods, respectively. Levels for all subscales scores were similarly high.

Table 1. Readability ease and grade level scores of the original Mobile App Rating Scale and the simplified user version of the scale (uMARS).

MARS[a] version	Reading ease	Readability level	Grade level	Reading age
Original	47.2	Difficult	9.5	15-16 years old
uMARS[a]	58.0	Plain English – fairly difficult	7.9	12-13 years old

[a] MARS: Mobile App Rating Scale; uMARS: user version of the MARS.

Table 2. Test-retest reliability of the user version of the Mobile App Rating Scale (95% CI).

Subscale/item		1- to 2-month period (N=113)	3-month period (N=74)
Engagement		.71 (.66-.76)	.73 (.67-.78)
1	Entertainment	.60 (.41-.72)	.75 (.61-.85)
2	Interest	.69 (.55-.79)	.67 (.48-.79)
3	Customization	.61 (.44-.73)	.53 (.25-.70)
4	Interactivity	.55 (.35-.69)	.69 (.51-.81)
5	Target group	.72 (.59-.80)	.73 (.57-.83)
Functionality		.62 (.54-.68)	.69 (.61-.76)
6	Performance	.54 (.34-.69)	.71 (.53-.81)
7	Ease of use	.65 (.49-.76)	.72 (.55-.82)
8	Navigation	.62 (.45-.74)	.67 (.48-.79)
9	Gestural design	.61 (.44-.73)	.65 (.44-.78)
Aesthetics		.58 (.48-.66)	.68 (.59-.76)
10	Layout	.39 (.11-.58)	.48 (.18-.67)
11	Graphics	.70 (.56-.79)	.77 (.63-.85)
12	Visual appeal	.63 (.46-.75)	.80 (.68-.87)
Information		.48 (.38-.57)	.52 (.40-.62)
13	Quality of information	.48 (.24-.64)	.44 (.11-.65)
14	Quantity of information	.48 (.24-.64)	.32 (.08 to .57)
15	Visual information	.42 (.16-.60)	.75 (.61-.84)
16	Credibility of source	.51 (.29-.66)	.63 (.41-.77)
Total uMARS[a]		.66 (.63-.68)	.70 (.67-.78)
Subjective items		.70 (.64-.75)	.71 (.64-.77)
17	Would you recommend	.84 (.76-.89)	.75 (.60-.84)
18	How many times	.44 (.18-.61)	.48 (.17-.67)
19	Would you pay	.81 (.73-.87)	.82 (.71-.89)
20	Overall (star) rating	.71 (.59-.80)	.77 (.63-.85)

[a] uMARS: user version of the Mobile App Rating Scale.

Discussion

This study developed and tested an app user version of the original MARS to assist app developers and researchers with evaluating the quality of mHealth apps. The uMARS (Multimedia Appendix 1) provides a 20-item measure that includes 4 objective quality subscales—engagement, functionality, aesthetics, and information quality—and 1 subjective quality subscale. One further subscale, consisting of 6 items is added to measure users' perceived impact of the evaluated app. The study demonstrated that the uMARS had excellent internal consistency for the full scale and good levels for all subscales. It is reassuring that even after a 3-month delay between ratings, test-retest reliability of the total score was good, and test-retest reliabilities of its subscales were *fair* to *good*, with the *engagement* and *subjective* subscales being particularly robust.

These results indicate that the uMARS provides a reliable measure of app quality in target users. Replication of the current results with multiple types of mHealth apps is required to provide additional confidence in its performance. Tests of its sensitivity to improvements in app quality and an examination of its ability to predict outcomes of mHealth apps are also needed. As the uMARS may potentially have applications beyond mHealth, tests of its performance in other domains are also indicated.

Current indications are that the uMARS will offer an unprecedented ability to readily obtain rich information from users about mobile apps. The scale can be used to obtain user feedback on the quality of mobile apps during the development and testing process, which may result in overall improvements in their quality.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

[PDF File (Adobe PDF File), 53KB - mhealth_v4i2e72_app1.pdf]

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Abbreviations

ICC: interclass correlation coefficient
MARS: Mobile App Rating Scale
mHealth: mobile health
RCT: randomized controlled trial

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Original Paper

Older Adults' Experiences Using a Commercially Available Monitor to Self-Track Their Physical Activity

Siobhan K McMahon[1*], PhD, MPH, GNP-BC; Beth Lewis[2*], PhD; Michael Oakes[3*], PhD; Weihua Guan[3*], PhD; Jean F Wyman[1*], PhD, RN, GNP-BC; Alexander J Rothman[4*], PhD

[1]University of Minnesota, School of Nursing, Minneapolis, MN, United States
[2]University of Minnesota, School of Kinesiology, Minneapolis, MN, United States
[3]University of Minnesota, School of Public Health, Minneapolis, MN, United States
[4]University of Minnesota, Department of Psychology, Minneapolis, MN, United States
[*]all authors contributed equally

Corresponding Author:
Siobhan K McMahon, PhD, MPH, GNP-BC
University of Minnesota
School of Nursing
308 Harvard Street SE
Minneapolis, MN, 55455
United States
Phone: 1 2182903422
Fax: 1 2182903422
Email: skmcmaho@umn.edu

Abstract

Background: Physical activity contributes to older adults' autonomy, mobility, and quality of life as they age, yet fewer than 1 in 5 engage in activities as recommended. Many older adults track their exercise using pencil and paper, or their memory. Commercially available physical activity monitors (PAM) have the potential to facilitate these tracking practices and, in turn, physical activity. An assessment of older adults' long-term experiences with PAM is needed to understand this potential.

Objective: To assess short and long-term experiences of adults >70 years old using a PAM (Fitbit One) in terms of acceptance, ease-of-use, and usefulness: domains in the technology acceptance model.

Methods: This prospective study included 95 community-dwelling older adults, all of whom received a PAM as part of randomized controlled trial piloting a fall-reducing physical activity promotion intervention. Ten-item surveys were administered 10 weeks and 8 months after the study started. Survey ratings are described and analyzed over time, and compared by sex, education, and age.

Results: Participants were mostly women (71/95, 75%), 70 to 96 years old, and had some college education (68/95, 72%). Most participants (86/95, 91%) agreed or strongly agreed that the PAM was easy to use, useful, and acceptable both 10 weeks and 8 months after enrolling in the study. Ratings dropped between these time points in all survey domains: ease-of-use (median difference 0.66 points, *P*=.001); usefulness (median difference 0.16 points, *P*=.193); and acceptance (median difference 0.17 points, *P*=.032). Differences in ratings by sex or educational attainment were not statistically significant at either time point. Most participants 80+ years of age (28/37, 76%) agreed or strongly agreed with survey items at long-term follow-up, however their ratings were significantly lower than participants in younger age groups at both time points.

Conclusions: Study results indicate it is feasible for older adults (70-90+ years of age) to use PAMs when self-tracking their physical activity, and provide a basis for developing recommendations to integrate PAMs into promotional efforts.

Trial Registration: Clinicaltrials.gov NCT02433249; https://clinicaltrials.gov/ct2/show/NCT02433249 (Archived by WebCite at http://www.webcitation.org/6gED6eh0I)

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KEYWORDS

Aged; Mobile Health; Self-Appraisal; Physical Activity; Motivation; Monitoring; Ambulatory; Wearables

Introduction

Physical activity (PA) confers health benefits across older adult populations, including those with chronic conditions, and supports their autonomy and quality of life as they age [1]. Fewer than 1 in 5 older adults engage in recommended levels of physical activities [2]. Commercially available physical activity monitors (PAM) have the potential to facilitate PA and thus become a valuable adjunct to increasing PA levels [3]. To date, owners of such PAMs are predominantly young technology enthusiasts and those interested in confirming their fitness levels [4]. Design and marketing strategies for PAMs tend to track these patterns. Thus, it is not surprising that few older adults own [5] or use [6] such devices. However, the personalized data and support provided by PAMs could be beneficial to older adults.

Background

Many older adults currently track their exercise, weight, or diet using pencil and paper or their memory [6]. Self-tracking PA (a form of self-monitoring outcome behavior) is a behavioral-change technique shown to increase older adults' self-efficacy for exercise [7] and their initiation of new PA behavior [8]. Commercially available activity monitors have the potential to augment the PA self-tracking practices of older adults.

There is growing evidence refuting the perception that older adults are not interested in, or do not have the ability to use, technology in their everyday life. Older adults report having interests in using technology, particularly when it is easy to use, convenient (eg, fits well into daily routines), and benefits their health and wellness [9]. In a 2014 survey of older adults, 78% report using mobile phones (22% smartphones); 62% report using tablets; and 59% report using the Internet, primarily to communicate with family and friends, to shop, and to obtain health information [10].

Given that older adults practice self-tracking and have interests in (and the abilities to use) technology, researchers have begun to examine their acceptance of PAMs. Initial findings suggest that older adults evaluate PAMs positively in terms of comfort, ease of installation, and usefulness [11]. Participants also report having an interest in purchasing and using PAMs in the future [11,12]. Although promising, these initial studies assessed the experiences of older adults over short durations, ranging from three days to three weeks, which may not represent long-term experiences. For example, 6-12 months after purchasing PAMs, many younger owners report abandoning them [5]. Another limitation of initial studies is that participants were, on average, in their mid-60s. The experiences of 65-year-olds may not represent the experiences of people in their 70s, 80s, and 90s. Further evaluation of older adults' long-term experiences with PAMs will build on this research and provide a basis for developing recommendations regarding the use of PAMs to facilitate PA tracking practices in this population.

Study Objectives

The purpose of this study was to assess the short-term (10 week) and long-term (8 month) experiences of community-dwelling older adults using a popular, commercially available PAM (Fitbit One) to self-track their PA. The technology acceptance model (TAM) guided this assessment. The TAM posits that a person's intention (*acceptance*) to use a new technology such as a PAM depends on their perceptions of its *ease-of-use* and its *usefulness* [13]. Research questions at the short-term and long-term assessment time points were:

1. Do older adults believe that PAMs are easy to use?

2. Do older adults believe data provided by a PAM is valuable and useful for self-monitoring and supporting their PA?

3. Do older adults with experience using a PAM intend to continue using it to track their PA?

In addition to these TAM-guided research questions, we sought to determine the extent to which participants' perceptions and evaluations of PAMs differ between men and women, by level of educational attainment, and by age.

Methods

Design

This prospective study included participants from a randomized controlled trial (RCT) testing a fall-reducing PA promotion intervention in community-dwelling older adults [14]. All study participants received a PAM (Fitbit One) to facilitate their self-tracking practices throughout the 8-month study. Participants' experiences were assessed after two main phases of the RCT: an intervention phase and a follow-up phase. During the 10-week intervention phase, participants had regular contact with intervention staff and structured support for using their PAMs. During the six-month follow-up phase, participants were left to use their PAMs independently. Thus, the respective 10-week and 8-month assessments represent short-term experiences using a PAM with structured support and longer-term experiences using a PAM without structured support. The Institutional Review Board at the University of Minnesota (UMN) approved the study protocol.

Participants

The 95 participants in this study were community-dwelling older adults recruited via newspaper advertisements and flyers, which were placed in locations frequented by older adults living in Minneapolis, Minnesota between April and August 2014. Eligibility criteria included being 70 years old or greater, having the ability to walk, having the ability to speak English, having levels of PA below recommended guidelines [1], and not having a diagnosis of dementia. As the parent RCT was a pilot study, a convenience sample was used. Participants were given an incentive of $20 to complete each interview (3 for the current study) and invited to keep their PAM after completing the study.

Procedures

Fitbit Ones were used in this study for four reasons. First, their displays provide data about several PA indicators (eg, steps, floors, distance, activity bouts). This level of detail makes them usable as stand-alone PAMs for individuals who cannot, or prefer not to, access the Internet. Second, there is an emerging body of evidence regarding the accuracy of the Fitbit One to

sense PA [15-17] and estimate energy expenditure [11,18] in older adults when compared to observations of step counts and other accelerometers used in research. Third, research platforms are available that securely aggregate, store, analyze, and export de-identified data from many PAM wearers [19]. Finally, features of the Fitbit One used in this study were consistent with the theoretical basis [20] and intervention strategies used in the parent RCT (eg, selectively share data, individualize PA goals, self-monitor behavioral outcomes).

Participant feedback during the first few weeks of the study informed the refinement of PAM-related protocols. The first refinement was to decrease the manufacturer-set goals within the PAM (eg, 10,000 steps, 5 miles) to be safe and more relevant for older adult populations (eg, 1500 steps, 0.5 miles). The second was to use display characteristics most valued by older adults in this study, including greetings (eg, “Hi Tom.”), chatter (eg, “You rock.”, “Ready?”), steps, distance, and a flower that grows with continuous activity. Finally, participants were given the option to use graphing worksheets developed for those wanting to visualize their PA trends, but without access to (or willingness to use) the Internet for visualizing their PA dashboards.

Participants received a basic orientation when first enrolling into the RCT, assistance with troubleshooting for the next 10 weeks, and limited assistance after that. Upon enrollment, participants received a 15-30 minute basic orientation introducing the purpose of the PAM and demonstrating its core functions: charging, wearing, and reading displays. Participants were encouraged to demonstrate the skills they just learned and to ask questions. Individuals were also encouraged to use the project telephone number when in need of troubleshooting assistance or advanced orientation for operations, such as changing personal goals within the PAM and using a smartphone app to visualize their data. After being in the RCT for 10 weeks, participants received only limited troubleshooting assistance via the project telephone number. Approximately 10 individuals called during this time-frame with questions and challenges solvable by phone. Examples include getting their PAM out of its sleep mode, replacing lost or damaged PAMs, and synchronizing difficulties.

Research assistants (RA) collected data during one-on-one interviews using standardized procedures at three time points. The first time point was within one week of enrolling into the RCT; RAs administered a baseline characteristic questionnaire comprised of clinical and demographic variables. The second and third time points were 10 weeks and 8 months post-RCT enrollment; RAs administered technology surveys. Research Electronic Data Capture (REDCap) is a secure, web-based application designed to support data capture and management for research studies hosted at the UMN, that was used to collect and manage all data [21].

Measures

Baseline characteristic questionnaires included the following demographic and clinical variables: self-reported age, sex, educational attainment, race, ethnicity, technology experience, and health conditions. The 10-item technology survey, adapted from previous usability and acceptability studies [13,22] addressed the 3 TAM domains (perceived *ease-of-use*, perceived *usefulness*, and *acceptance*), using a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Perceived *ease-of-use* is the degree to which a person believes technology use is free of effort. This TAM domain, linked to the research question asking if older adults believe that PAM are easy to use [13,22], was measured using five items (Cronbach alpha=.80, see items 1-5 in Multimedia Appendix 1). Perceived *usefulness* is the degree to which a person believes a technology provides useful information. This TAM domain, linked to the second research question about older adults' beliefs regarding the value and usefulness of data provided by a PAM [13], was measured using four items (Cronbach alpha=.80, see items 6-9 in Multimedia Appendix 1). *Acceptance* is the degree to which a person intends to use technology. This TAM domain, linked to the third research question regarding whether older adults intend to continue using a PAM to self-track their PA [12], was measured using one item (see item 10, Multimedia Appendix 1).

Data Management and Analysis Plan

The online designer within REDCap enabled the creation of user-friendly case report forms for the baseline characteristic questionnaire and the technology survey (see Multimedia Appendix 1) with real-time data entry validation (completion), audit trails, and the ability to schedule participant interviews 10 weeks and 8 months after study enrollment. Research assistants entered real-time data into a REDCap case report forms using tablet computers during interviews with participants.

De-identified data from aggregated case report forms were exported into SPSS 22 and analyzed in two phases. First, univariate analyses were conducted to summarize participants’ baseline characteristics and survey scores. The distributions of individual mean scores within each survey domain, assessed by visual inspection of histograms, were not normally distributed. Therefore, the second phase of analysis used non-parametric inferential statistics. Median differences in ratings between 10-week and 8-month time points were analyzed using the Wilcoxon signed-rank test, a non-parametric analog to the paired samples t-test. The Mann-Whitney U and the Kruskal-Wallis tests, non-parametric analogs to independent-samples t-tests and one-way analysis of variance, were used to test median differences between multiple groups (eg, sex, age, education) at the same time point. Groupings for educational attainment (high school, at least some college, or college graduate) and age (70-74, 75-79, or 80+) are consistent with Smith’s survey of older adults and technology use [10]. Bonferroni corrections were made when multiple hypotheses were tested simultaneously. Adjusted P-values are presented.

Results

Baseline Demographic Characteristics

Ninety-five community-dwelling older adults participated in the study, most of whom were women (71/95, 75%) with some college education (68/95, 72%), ranging in age from 70 to 96 years of age (mean 79.8, SD 6.8). See Table 1 for baseline characteristics.

Table 1. Baseline characteristics of study participants (N=95).

		n (%)
Age	70-74	31 (33%)
	75-79	25 (26%)
	80+	39 (41%)
Race	African American	23 (24%)
	White	72 (76%)
Sex	Female	71 (75%)
	Male	24 (25%)
Education	Less than High School	3 (3%)
	High School	21 (22%)
	Some College	24 (26%)
	College Graduate	44 (46%)
	Refused	3 (3%)
Prior Technology Experience	Used Smart Phone	9 (9%)
	Used Laptop or tablet	31 (33%)
	Used PAM	1 (1%)
Chronic Conditions	Diabetes	27 (28%)
	Heart Disease	32 (34%)
	Lung Disease	9 (10%)
	Arthritis	65 (68%)

Ease-of-use

Overall, participants rated the *ease-of-use* domain positively at 10 weeks (median 4.60/5) and 8 months (median 4.20/5). Median differences between these time points were statistically significant as indicated by a Wilcoxon signed-rank test, $P<.001$. Follow-up tests revealed ratings of three items dropped significantly: *Most people, like me, could easily learn to use a Fitbit One* (median difference 0.23 points, $P=.003$); *I look at my Fitbit One at least once per day (*median difference 0.23 points, $P=.001$); and *I have sufficient information to help me get my personal data from my Fitbit One* (median difference 0.21 points, $P=.008$). Most participants (78/95, 82%) continued to agree or strongly agree with items in this domain after 8 months of ownership. Figure 1 illustrates the distribution of participant ratings (range 1-5) for the five items within this domain at 10 weeks and 8 months.

Usefulness

Overall, participants rated the perceived *usefulness* domain positively at 10 weeks (median 4.13/5) and 8 months (median 3.98/5). Median differences between these time points were not statistically significant as indicated by a Wilcoxon signed-rank test ($P=.19$). Most participants (65/95, 68%) continued to agree or strongly agree with items in this domain after 8 months of ownership. Figure 2 illustrates the distribution of participant ratings (range 1-5) for the four items within this domain at 10 weeks and 8 months.

Acceptance

Overall, participants rated the *acceptance* domain positively at 10 weeks (median 4.54/5) and 8 months (median 4.25/5). Median differences in ratings between these time points were statistically significant as indicated by a Wilcoxon signed-rank test, $P=.025$. Although ratings declined, most participants (82/95, 86%) continued to agree or strongly agree with this item after 8 months of use. Figure 3 illustrates the distribution of participant ratings (range 1-5) of this one-item domain.

Figure 1. Perceived Ease-of-Use of Technology at 10 weeks and 8 months.

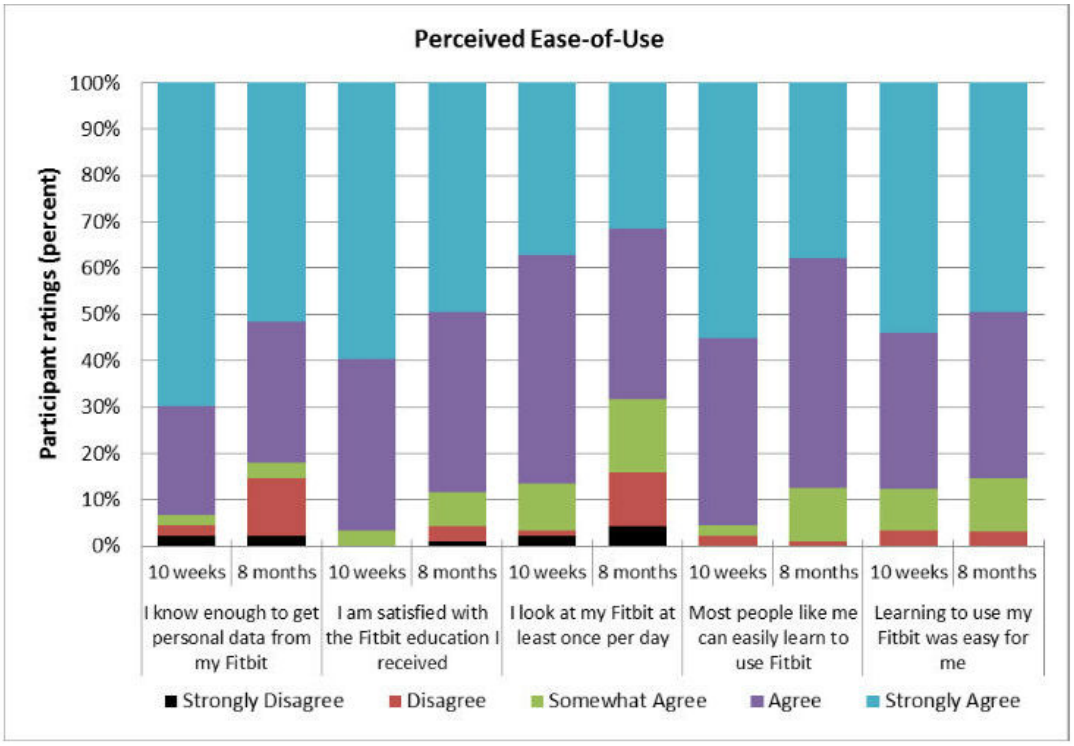


Figure 2. Perceived Usefulness of Technology at 10 weeks and 8 months.

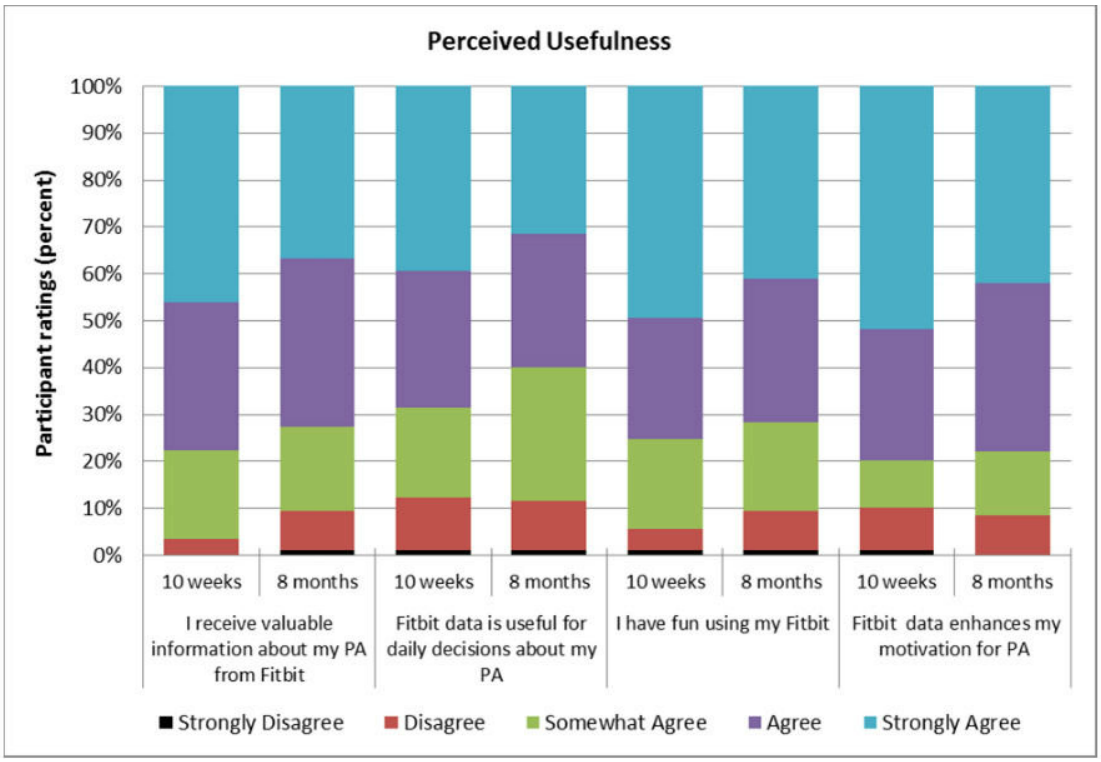
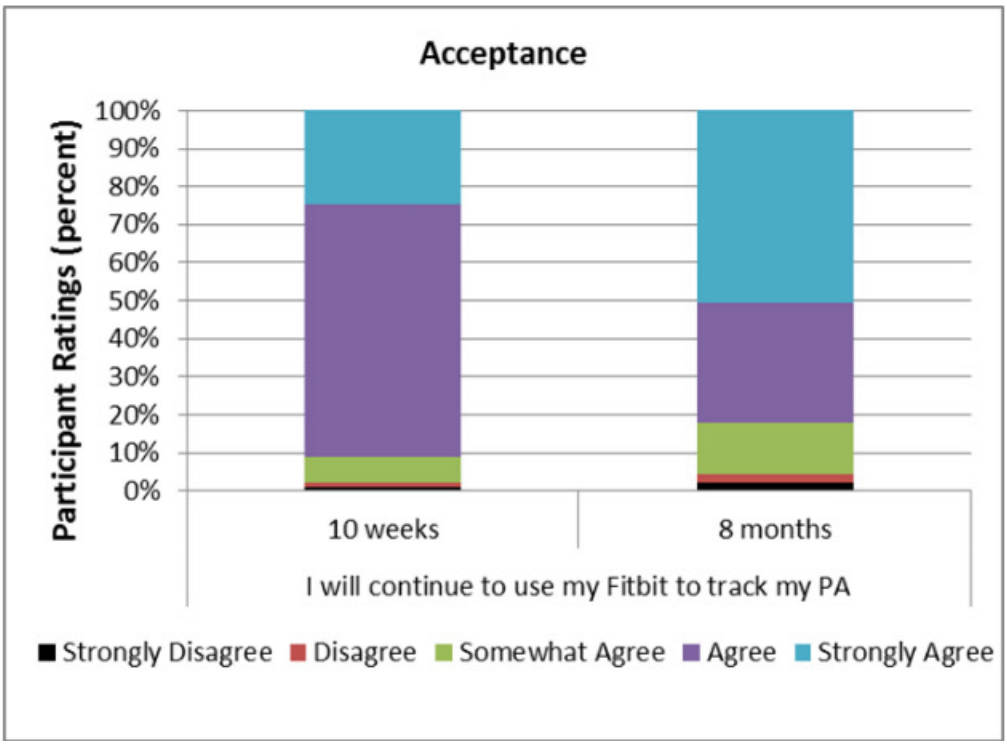


Figure 3. Technology Acceptance at 10 weeks and 8 months.



Participant Ratings by Sex, Education Attainment, and Age

Differences between men and women's median ratings of the three survey domains were not statistically significant as evidenced by Mann-Whitney U tests for *ease-of-use* at 10 weeks (median difference 0.11, *P*=.91) and 8 months (median difference 0.40, *P*=.65); *usefulness* at 10 weeks (median difference 2.00, *P*=.14) and 8 months (median difference 1.02, *P*=.19); and *acceptance* at 10 weeks (median difference 0.40, *P*=.77) and 8 months (median difference 0.23, *P*=.27).

Differences in ratings between participants in the three education attainment groups (high school, some college, or college graduates) were not statistically significant, as evidenced by the Kruskal-Wallis test of mean rank differences for: *ease-of-use* at 10 weeks (range of mean ranks 38-49, *P*=.21) and 8 months (range of mean ranks 44-49, *P*=.55); *usefulness* at 10 weeks (range of mean ranks 40-47, *P*=.51) and 8 months (range of mean ranks 41-48, *P*=.58); and *acceptance* 10 weeks (range of mean ranks 43-47, *P*=.56) and 8 months (range of mean ranks 40-49, *P*=.33).

Differences in ratings between participants in the three age groups were statistically significant at 10 weeks for all three survey domains: *ease-of-use*, χ^2_2 = 13.83, *P*=.002; *usefulness*, χ^2_2 = 20.41, *P*<.001; and *acceptance* χ^2_2 = 12.52, *P*=.002. Follow-up pairwise comparisons revealed lower ratings for the *ease-of-use* domain among participants in the 80+ age group (mean rank 33) compared to those in the 70-74 age group (mean rank 53, *P*=.005), and those in the 75-79 age group (mean rank 55, *P*=.006). Participants in the 80+ age group also rated the *usefulness* domain lower (mean rank 31) than those in the 70-74 age group (mean rank 51, *P*=.004), and the 75-79 age group (mean rank 62, *P*<.001). Finally, participants in the 80+ age group also rated the *acceptance* domain lower (mean rank 36) than those in the 70-74 age group (mean rank 54, *P*=.005) and the 75-79 age group (mean rank 50, *P*=.019).

Differences in ratings between participants in the three age groups at 8 months were also statistically significant for *ease-of-use*, χ^2_2 = 6.89, *P*=.032; *usefulness*, χ^2_2 = 6.90, *P*=.032; and *acceptance* χ^2_2 = 13.56, *P*=.001. Follow-up pairwise comparisons revealed lower ratings for the *ease-of-use* domain among participants in the 80+ age group (mean rank 39) compared to those in the 70-74 age group (mean rank 55, *P*=.036). Analyses also revealed lower ratings for *acceptance* among participants in the 80+ age group (mean rank 37), compared to those in the 70-74 age group (mean rank 59, *P*=.001). However, differences between age groups in ratings of the *usefulness* domain were not statistically significant (*P*>.067). Although ratings among participants in the 80+ age group were lower compared to younger age groups, most participants in this oldest age group (28/37, 76%) agreed or strongly agreed that the PAM was *easy to use*, *useful*, and *acceptable* after 8 months of ownership.

Discussion

The purpose of this study was to assess older adults' short and long-term experiences using PAM to self-track their PA. Overall, older adults evaluated the PAM as *easy to use*, *useful*, and *acceptable* with and without structured support. Although the *ease-of-use* and *acceptance* ratings decreased over time, and ratings were lower among those who were >80 years old compared to younger age groups, most ratings were positive.

Short-term (10 week) participant ratings across all three survey domains (perceived *ease-of-use*, *usefulness*, and *acceptance*) were positive and consistent with previous research [11,12].

Longer-term (8 month) follow-up ratings were mostly positive, but there were no comparable studies. Researchers at Endeavor Partners surveyed PAM owners (mostly younger adults) and found that more than 30% have abandoned their device within 8 months [5]. To compare, we estimated the 8-month abandon rate in this study by calculating the percentage of participants who either disagreed or strongly disagreed with the statement, "I will continue to use my Fitbit One to track my PA", which was 4%. Lower rates of abandonment by participants in this study may have been, in part, because of the structured support they received during the first 10 weeks of the study. It is also possible that older adults, more than younger populations, find PAMs have long-term utility.

Lower survey ratings by participants >80 years old, observed at both time points, are consistent with this age group's response to other technology-adoption surveys (all aspects of digital life) [10]. One possible explanation may be that there are age-related differences in individual technology adoption rates or initial decisions about using technology. Participants aged 70-79, more than participants >80 years, may have been *early adopters* or had lower levels of uncertainty when first introduced to Fitbit Ones [23]. These differences might also reflect a need for more time among participants >80 years old to learn new technology, compared to younger participants. Older adults have reported that they need someone to walk them through the process of using a new technology [10], and that social learning (learning new technology with at least one other person) is easier than learning alone with the aid of a manual [24]. These findings validate the need for limited support, especially while individuals are first learning PAM characteristics and making decisions about how the technology might be relevant to personal health-related values.

Limitations

This study had several limitations. The experiences of older adults in this sample were assessed using just one popular PAM; ratings of PAM usage and acceptance may vary over time and by model. A second limitation was that PAM usage in this study was in a context of high support, at least during the initial 10-week period. This level of support exceeds what new owners of commercially available PAMs typically acquire, such as tailoring manufacturer-set goals within PAMs to be consistent with typical goals of older adults, and providing participants who preferred not to use the Internet with tools to aid their visualizations of aggregate data. A third limitation is that TAM, the conceptual model used in this study, posits that the two main drivers of technology acceptance are perceived *usefulness* and perceived *ease-of-use*. Additional drivers may be important to consider in older adult populations, such as health benefits and emotional satisfaction [25,26]. Finally, the sample in this study was not representative of the general US population of older adults. The proportion of female participants in this study (71/95, 75%) was higher than that of older adults in the US population (59%), and the proportion of participants with college degrees (44/95, 46%) was higher than that of the US population (26%) [27].

Future Research

The findings of this study support future research to examine the facilitating potential of PAM activity trackers on older adults' PA, and hint at opportunities for new designs to optimize meaningful use. It is unlikely that ownership of a PAM, alone, will elicit changes in PA behavior [3]. Thus, examining the facilitative potential of PAMs will be most informative when using them as a medium for testing various engagement strategies [5] and behavioral change techniques [28]. Just as ownership will not drive behavior, nor will the designs of these PAMs. However, some tailoring of characteristics such data cuts and data visualization might improve the experiences of older adults using PAMs [29]. For example, visualization possibilities for older adults might be simplified, particularly within a single device. It will be worthwhile to explore how display options on PAMs, such as Fitbit One, might display relevant data cuts of weekly PA trends (eg, small bar graphs or other visualizations). Another possibility is to explore ways in which older adults can easily and selectively share their personal PA data (not including social media venues) with important others such as family, friends and healthcare providers. Exploration of new PAM designs tailored for older adults will yield the most information when they include an understanding of their unique preferences, capabilities, and limitations, as well as sensitivity to what might undermine their individual potential. Such an understanding will require person-centered design strategies, as recommended by experts in the fields of human-computer interaction, psychology, and gerontology [25,26,30,31].

Conclusion

This study provides valuable insights into older adults' short and long-term experiences with a commercially available PAM for self-tracking PA, the Fitbit One. Older adults with little technology experience, low levels of PA, as well as diverse PA goals and abilities, found the PAM *easy to use* and *useful* for self-tracking their PA. Thus, despite design and marketing strategies of PAMs that primarily target younger populations, it is feasible for older populations (70-90+ years of age) to use PAMs in ways that support their unique PA goals. These results support the potential of PAM technology to facilitate PA in older adults and provide a basis for developing recommendations for promoting such use.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Technology Survey.

[PDF File (Adobe PDF File), 46KB - mhealth_v4i2e35_app1.pdf]

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Abbreviations

PA: physical activity
PAM: physical activity monitor
RA: research assistant
RCT: randomized control trial
REDCap: Research Electronic Data Capture
TAM: technology acceptance model
UMN: University of Minnesota

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Original Paper

Development of a Wearable Cardiac Monitoring System for Behavioral Neurocardiac Training: A Usability Study

Akib A Uddin[1,2], MHSc; Plinio P Morita[2], PhD; Kevin Tallevi[2]; Kevin Armour[2], BID; John Li[2], MSc; Robert P Nolan[3], PhD, CPsych; Joseph A Cafazzo[1,2,4], PhD, PEng

[1]Institute of Biomaterials and Biomedical Engineering, Faculty of Medicine, University of Toronto, Toronto, ON, Canada

[2]Centre for Global eHealth Innovation, Techna Institute, University Health Network, Toronto, ON, Canada

[3]Cardiac eHealth & Behavioural Cardiology Research Unit, Toronto General Hospital, University Health Network, University of Toronto, Toronto, ON, Canada

[4]Institute of Health Policy, Management and Evaluation, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

Corresponding Author:
Akib A Uddin, MHSc
Centre for Global eHealth Innovation
Techna Institute
University Health Network
TGH/RFE Bldg, 4th Fl.
190 Elizabeth St
Toronto, ON, M5G 2C4
Canada
Phone: 1 416 340 4800 ext 4765
Fax: 1 416 340 3595
Email: akib.uddin@uhn.ca

Abstract

Background: Elevated blood pressure is one of the main risk factors for death globally. Behavioral neurocardiac training (BNT) is a complementary approach to blood pressure and stress management that is intended to exercise the autonomic reflexes, improve stress recovery, and lower blood pressure. BNT involves cognitive-behavioral therapy with a paced breathing technique and heart rate variability biofeedback. BNT is limited to in-clinic delivery and faces an accessibility barrier because of the need for clinical oversight and the use of complex monitoring tools.

Objective: The objective of this project was to design, develop, and evaluate a wearable electrocardiographic (ECG) sensor system for the delivery of BNT in a home setting.

Methods: The wearable sensor system, *Beat*, consists of an ECG sensor and a mobile app. It was developed iteratively using the principles of test-driven Agile development and user-centered design. A usability study was conducted at Toronto General Hospital to evaluate feasibility and user experience and identify areas of improvement.

Results: The *Beat* sensor was designed as a modular patch to be worn on the user's chest and uses standard ECG electrodes. It streams a single-lead ECG wirelessly to a mobile phone using Bluetooth Low Energy. The use of small, low-power electronics, a low device profile, and a tapered enclosure allowed for a device that can be unobtrusively worn under clothing. The sensor was designed to operate with a mobile app that guides users through the BNT exercises to train them to a slow-paced breathing technique for stress recovery. The BNT app uses the ECG captured by the sensor to provide heart rate variability biofeedback in the form of a real-time heart rate waveform to complement and reinforce the impact of the training. Usability testing (n=6) indicated that the overall response to the design and user experience of the system was perceived positively. All participants indicated that the system had a positive effect on stress management and that they would use it at home. Areas of improvement were identified, which focused primarily on the delivery of training and education on BNT through the app.

Conclusions: The outcome of this project was a wearable sensor system to deliver BNT at home. The system has the potential to offer a complementary approach to blood pressure and stress management at home and reduce current accessibility barriers.

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KEYWORDS

mobile health; smartphones; sensor devices and platforms; wireless technology; mobile applications; electrocardiography; biofeedback, psychology; blood pressure; stress, physiological; relaxation

Introduction

High blood pressure is one of the major global risks for mortality and the most important risk factor and leading cause of cardiovascular disease. It accounted for 7.5 million or 13% of all deaths globally in 2008 and affects approximately 30% of adults older than 25 years [1,2]. High blood pressure also has an extremely high economic burden on health care systems, with an estimated cost of more than $370 trillion, representing 10% of the global health care expenditures [2]. Because of its impact, controlling high blood pressure has been stated as an international health priority [1].

The 2 primary approaches to managing blood pressure levels are lifestyle modifications (diet and exercise) and pharmacological treatments (antihypertensive drugs) [3]. However, additional interventions may be required when medication side effects are severe, lifestyle changes are not sufficient to lower or maintain blood pressure, or the patient prefers nonpharmacologic treatment [4]. Behavioral approaches offer an additional, complementary option for patients in these groups.

Behavioral Neurocardiac Training

The Cardiac eHealth & Behavioural Cardiology Research Unit at Toronto General Hospital has developed an approach called "behavioral neurocardiac training" (BNT), which offers a complementary approach to managing stress and high blood pressure [5,6]. BNT aims to improve the patient's ability to recover from stressful stimuli and helps reduce unnecessary strain on their heart and blood vessels. Nolan et al [5,6] demonstrated that BNT reduced daytime systolic blood pressure by 2.4±0.9 mm Hg (P=.009) and 24-hour systolic blood pressure by 2.1±0.9 mm Hg (P=.03). This reduction was confirmed to be independent of pharmacologic interventions. BNT was also found to reduce symptoms on the Perceived Stress Scale (P=.001). BNT achieved these results by stimulating and exercising the autonomic reflexes, making them more efficient, and increasing total heart rate variability. As a result, vagal heart rate modulation was significantly increased, reducing the effect of stress and sympathetic activity on blood pressure [5,6].

BNT is a multistep process that involves cognitive-behavioral therapy for stress management and the training of a paced breathing technique to regulate recovery from stress. Pacing breathing at 6-10 breathes per minute elicits respiratory sinus arrhythmia (RSA), where heart rate synchronizes with breathing and there is increased oscillations in heart rate. This increases total heart rate variability (HRV), exercising the autonomic nervous system's reflexes and counteracting parasympathetic inhibition after stress [5,6].

This breathing technique is reinforced using HRV biofeedback. Biofeedback is the process of gaining greater awareness of aspects of one's physiology using monitoring equipment, with the aim of controlling it [7]. In BNT, the patient completes stress reactivity and recovery exercises that are complemented with real-time biofeedback. As they recover from stress using the paced breathing technique, monitors display a breathing pacer and HRV measures. These act as operant feedback to reinforce the patient's progress toward a therapeutic goal [5,6]. A clinician guides this process and helps the patient interpret the results.

Limitations of Existing Solutions

BNT is currently limited to clinical settings because of two main difficulties. First, it requires a number of complex physiological monitoring devices, including a 12-lead ECG for data collection and a desktop computer running customized data visualization software. The monitoring devices are physically large and costly, presenting a significant barrier for widespread deployment of this technique. Second, the existing interface for displaying the biofeedback and breathing pacer was designed for use with clinician oversight. The clinician would guide the patient, direct their attention to the appropriate areas of the screen, and help interpret the meaning of the information being provided. Without this guidance, the user could find the interface to be technically complex to interpret independently. These issues create an accessibility barrier, preventing alternative delivery methods.

Existing commercial solutions that attempt to address these barriers include the emWave system (HeartMath Inc, Boulder Creek, CA, USA), which is a portable, consumer-focused system for biofeedback at home [8]. However, the emWave system measures heart rate using photoplethysmography, which is not as accurate as ECG, the standard reference signal for HRV. This is the reason why commercially available wrist-worn sensors such as the Fitbit Charge HR and Apple Watch cannot replace the ECG sensor, despite having a more user acceptable form. With photoplethysmography, R-peaks are not as evident, and sampling frequency is low, making it difficult to perform the precise HRV calculations required for BNT biofeedback. Another difficulty with the emWave system is that it focuses solely on paced breathing, whereas BNT is a multistep process that includes cognitive-behavioral therapy in addition to the paced breathing exercises. At this time, there are no commercial solutions that offer all the features of BNT for home use.

Motivation and Objectives

Wearable wireless sensor systems represent a network of wearable computing devices that can be implanted or worn on the body to collect real-time physiological data [9,10]. These sensor systems consist of sensor nodes to collect and transmit physiological information and an aggregator unit that acts as a central hub to fuse, visualize, and provide feedback on the data. Such systems offer an opportunity for the delivery of BNT outside of the clinic by providing patients with access to real-time data at home. This approach could possibly reduce accessibility barriers to care and may empower the patient by enabling self-care [11].

The intersection of behavioral approaches for blood pressure management and the technological domain of wearable wireless

sensor systems has guided the development of this project. Our goal was to design, develop, and evaluate a wearable ECG sensor system for the delivery of BNT in a home setting. The system is intended for short-term use, whereby users take the system home and train on cognitive-behavioral therapy and paced breathing exercises through a series of sessions. Once trained, the goal is for users to be able to better manage their stress levels, without using the system.

This paper describes the design of *Beat*, a wearable sensor system that includes an ECG sensor and a mobile app, and discusses the results of the feasibility evaluation with focus on the usability of the system.

Methods

This comprehensive project involved the design, development, and evaluation of the *Beat* sensor system. The system is intended for use in home settings, with adult patients with elevated blood pressure as the target audience. The development of the *Beat* was conducted in 3 major phases. Phase 1 and 2 included the development of the ECG sensor and BNT mobile app respectively. Phase 3 included the feasibility evaluation of the system.

Phase 1: Electrocardiographic Sensor Requirements and Development Process

The *Beat* sensor was designed to capture and wirelessly transmit a user's ECG data in real-time to the mobile phone. The primary design objectives were a small device footprint, less weight, and an exceptional user experience (usability). These are extremely important in making the sensor compact and unobtrusive. These attributes can also affect user experience and general comfort. Furthermore, a systematic literature review identified such features as the most important by users of wearable sensors. As per the user-centered approach, user preferences are a key influencer of whether the device gains acceptance among users and is actually used for its intended purpose [12,13].

Technical objectives include good signal quality, long battery life, and user safety. Signal quality is an important requirement for accurate calculation and analysis of HRV. A long battery life allows for multiple uses without recharging, reducing disruptions to the user's daily routine. Finally, as the device is patient worn and intended for home use, the safety of the user is of utmost importance.

The *Beat* sensor was developed following an iterative development process with several iterations of prototypes created and refined into the final design. Verification and validation testing were also conducted to ensure quality and that all user requirements were met. The development process was managed under the International Organization for Standardization (ISO) 13485 standard, which defines the quality management process for the design and manufacture of medical devices [14].

Phase 2: Behavioral Neurocardiac Training Mobile App Requirements and Development Process

The BNT app was designed to guide the user through the BNT exercises and provide real-time HRV biofeedback. This required the app to communicate with the *Beat* sensor in real time and process data for HRV analysis. The key design objective was to have a patient-friendly interface for ease of use and user satisfaction. This is essential as the system is intended for use in home settings, without any clinical guidance. The interface must be able to guide the user and help them interpret what is happening. Furthermore, the app must be able to process ECG data and provide HRV biofeedback in real time, as required by BNT.

The BNT app was developed on the BlackBerry 10 mobile platform, as it provided Bluetooth Low Energy support and more control over connection parameters, compared to other mobile platforms. Development followed an iterative fashion using the Agile software methodology [15]. Verification and validation testing were also conducted, and the project was managed under the ISO 13485 standard.

Phase 3: Feasibility Study

The purpose of the feasibility study was to evaluate usability, user interaction, and satisfaction with the sensor system to identify areas of improvement. These were accomplished through usability testing, observations, and qualitative questionnaires.

The feasibility study was conducted at the Cardiac eHealth and Behavioural Cardiology Research Unit at Toronto General Hospital in Toronto, Canada, in July and August, 2014. Participants were adults aged between 24-74 years and were recruited through flyers posted at Toronto General Hospital. Those who volunteered attended a single 1-hour session at the hospital, where they tested the system and provided their feedback. During the session, participants were asked to complete 4 main tasks, which included (1) usability testing of the wearable sensor system (users were asked to set up, connect, and wear the system); (2) completing 1 lesson of the BNT app; (3) completing a paper-based usability questionnaire (17 questions with 5-point Likert scale, developed by the study team to identify participant perceptions and overall satisfaction with the system); and (4) debriefing interview (conducted by a study team member).

There was a sample size of 6 participants based on the fact that the majority of usability issues can be detected with 5 participants [16]. This experiment was approved by the Institutional Research Ethics Board (Ref No: 13-6888-AE).

Results

The results of this study are presented following the same 3 phases outlined in the methodology section.

Phase 1: Beat Wearable Electrocardiographic Sensor

The *Beat* sensor was developed as part of an iterative design process, as shown in Figure 1. Initial concepts were generated on paper (Figure 1 a,b), exploring different approaches for signal collection and body attachment. After several conceptual

iterations, a patch design was chosen as it offers several advantages. First, the patch allows the electronics, signal collection, and body attachment components to be condensed into a small, compact package. This allows for a device with a small footprint and less weight that can be as unobtrusive as possible. Second, a patch was expected to be easy for users to wear, as a user only has to snap on electrodes and place the single unit on their chest, without having to place individual electrode locations. Finally, the patch allowed for the use of standard ECG electrodes, which provide a stable skin–electrode interface to improve signal quality and reduce noise.

An early functional prototype of the patch (Figure 1c) was developed using vertically stacked circuit boards to minimize footprint and flexible plastic to orient electrodes. This prototype successfully demonstrated signal collection and transmission, but had a high device profile and did not flex enough to the contour of the body.

Further iterations of the sensor (Figure 1d) addressed these issues and improved the overall aesthetic of the design. Horizontally placed boards were used to reduce the device profile with only a small increase in footprint, allowing the sensor to be unobtrusive and worn under clothing. The modular design addresses safety requirement by preventing users from ever being directly connected to line power, as the charging port is only exposed when the electronics module is disconnected from the patch.

The final design of the *Beat* sensor (Figures 2 and 3) is a modular patch with 3 components—electronics, patch, and electrodes. The electronics module houses and protects the sensor circuit and battery. Parts selection focused on components with low power consumption and small physical footprints. The final design uses an analog front end (ADS1293; Texas Instruments Inc, Dallas, TX, USA) to capture ECG at 260 samples per second, which meets the minimum requirements for accurate R-peak detection that is required HRV analysis [17]. A Bluetooth Low Energy system-on-chip radio (CC2541; Texas Instruments Inc, Dallas, TX, USA) is used to transmit the data to a mobile phone. Finally, an 110 mAh rechargeable lithium polymer-ion rechargeable battery supplies power. This battery provides a balance between physical size and power capacity and allows ECG streaming for 3.5 hours, exceeding the length of a BNT session (1 hour). As a real-time sensing and streaming device, the sensor does not store any data and has no memory.

The patch module is in the shape of a triangle that places the signal collection electrodes horizontally across the chest wall, and the right leg drive electrode is placed in between and below to reduce noise. The signal-collecting electrodes are separated by 10 cm in the final design to balance ECG signal quality and device size. The electronics module connects to the on-body patch through a clip mechanism and uses metal contacts for signal transfer. In this project, the sensor uses three Red Dot Repositionable electrodes (Product # 2660; 3M Company, Maplewood, MN, USA) to collect the signal and adhere the device to the user's body. These electrodes are designed for easy application and have a large conductive area and strong adhesion [18].

The enclosure is tapered with a low profile to be less obtrusive to the user. The main enclosure is composed of acrylonitrile butadiene styrene plastic and the on-body patch is composed of flexible rubber silicone. Acrylonitrile butadiene styrene plastic offers excellent impact resistance and has less weight, whereas flexible silicone rubber is an inert material that is familiar to users and can be easily cleaned [19].

The sensor is designed as a simple repositionable device that can be worn on multiple occasions and be easily adjusted for user preference or clothing. Figure 4 describes the recommended patch placement areas on the body. These are based on the standard lead I ECG electrode placement and research on electrode placement for single-lead applications [20,21].

As part of the ISO 14385 development process, the sensor passed through full verification and validation testing. This was to ensure all user and nonfunctional requirements were met and that the sensor collected ECG data accurately at the required sampling frequency. This included testing on a YellowJacket ECG simulator (Advantage Medical Cables Inc, Coral Springs, FL, USA) to verify that the ECG signal was collected accurately. The collected signal was analyzed on a computer and compared to the expected signal. Test execution was manual, with all test scenarios passing successfully.

Figure 1. (a) Paper concept of modular design. (b) Paper concept of patch positioning. (c) Early functional prototype with vertical boards and flexible plastic. (d) Intermediate prototypes with horizontal boards and rubber patch.

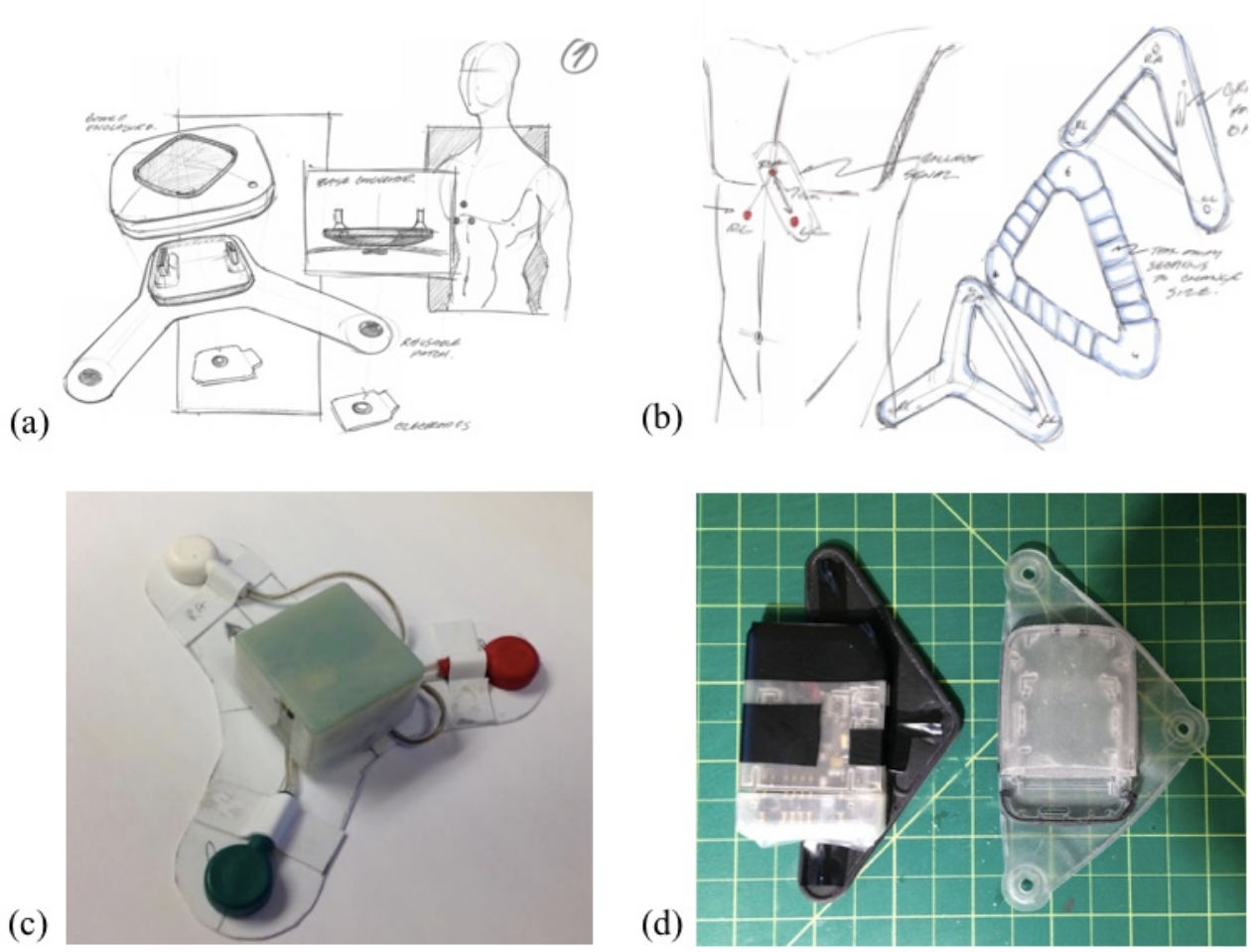
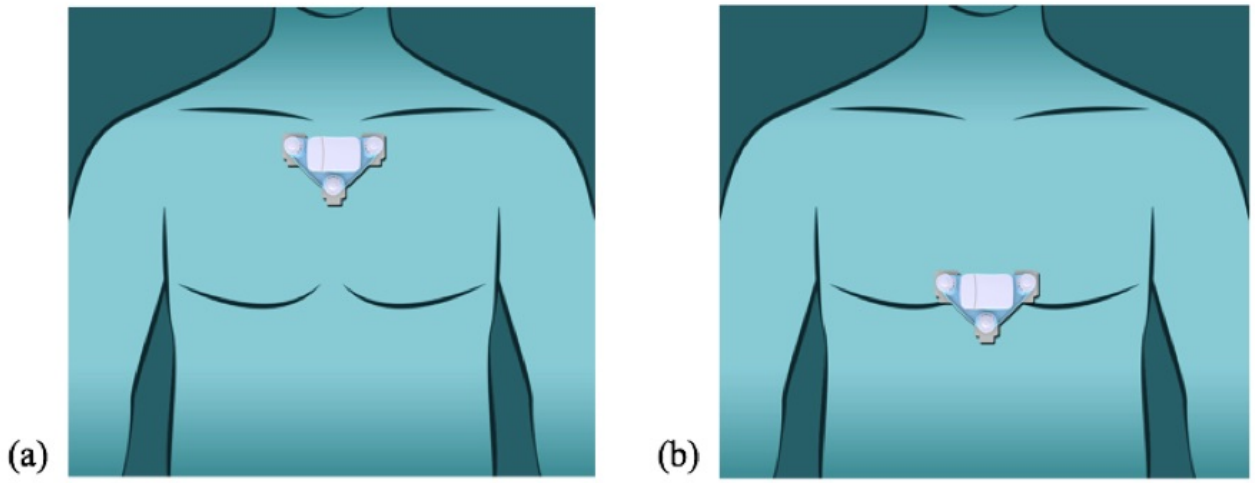


Figure 2. Final design of the Beat wearable ECG sensor with electrodes attached.

Figure 3. Individual components of the Beat wearable ECG sensor showing the electronics module and patch module.

Figure 4. (a) Primary patch placement for lead I ECG. (b) Secondary patch placement.



Phase 2: Beat Behavioral Neurocardiac Training App

The *Beat* BNT app serves to coach and guide the user through the BNT lessons, while providing real-time HRV biofeedback. The app presents BNT as a series of 5 lessons. Each lesson gradually introduces the users to BNT and paced breathing, goes through cognitive-behavioral therapy for stress management, and provides opportunities to practice the paced breathing technique and review their performance. As the app is intended for home use, it essentially takes the place of the clinician and guides the user through exercises using audio recordings, on-screen text, and interactive components.

The core exercise completed during each lesson is a stress reactivity and recovery protocol. It is used to reinforce the impact of the breathing technique and build the user's skill in maintaining a slow, controlled breathing rate. There are 3 main components—stress task, guided stress recovery with HRV biofeedback, and performance review. Screenshots of the user interface for each of these components are displayed in Figure 5.

Figure 5. The user interface of the BNT application during each stage of the stress reactivity and recovery protocol.

Stress Task

As part of the BNT exercises, users are exposed to mild-to-moderate stress tasks to engage physical or emotional arousal before they are guided in recovery using biofeedback. As with the existing in-clinic BNT protocol, the app uses a combination of physical and cognitive stress tasks that include seated leg raise, fist clench, serial addition, serial subtraction, and serial letters. Physical stress tasks are accompanied with real-time plots of HRV to highlight the impact of stress on heart activity. Cognitive stress tasks are adapted from the standardized cognitive tests and use a set of multiple-choice questions to test the user's working memory, attention, math abilities, and pattern recognition to induce mild-to-moderate stress. For each stress task, the user is presented with instructions and is oriented to complete the task for 1 minute. With each lesson, the stress tasks increase with difficulty to counteract the training effect.

Guided Stress Recovery With Heart Rate Variability Biofeedback

Once the users have been exposed to stressful stimuli, they are guided in stress recovery using the biofeedback interface. This interface provides the users with real-time biofeedback while guiding them in maintaining a slow, controlled breathing rate. As the users pace their breathing rate, the interface attempts to demonstrate the action–reaction perspective, where the user performs the breathing exercises (action) to elicit increased HRV (reaction or target outcome).

The main form of biofeedback used in the app is heart rate, derived in real-time from ECG captured by the *Beat* sensor. The heart rate waveform acts as a form of operant feedback, providing users with a real-time view of their physiology and how it is changing during the breathing exercise. When the users pace their breathing correctly, they see a quasi-sinusoidal heart rate waveform owing to the effect of the RSA. The biofeedback interfaces displays both a 1-minute window of real-time heart rate and a goal waveform demonstrating the target pattern and asks users to visually compare them to see progress toward the goal. The interface also presents a breathing pacer that can be adjusted to a specific breathing rate. It provides visual cues to the user on when they need to inhale, exhale, and hold breath in order to match the set breathing rate. This helps guide the users in slowing their breathing rate and maintaining a steady rhythm. The pacer serves only a demonstrative purpose and does not display the user's actual breathing rate.

Review

Once the users have completed stress recovery, the app displays review screens that present an overall view of their performance during the exercise. Performance is measured by heart activity in the form of heart rate and time domain HRV measures. The performance reviews compare the measures both within and between lessons to highlight the impact of the breathing technique over time. The within-lesson review attempts to highlight the effect of stress tasks on heart activity and the effect of paced breathing and biofeedback in recovery.

Software Algorithm Testing

Verification, integration, and validation testing were also conducted for the app. This was to ensure that the app communicated with the sensor, processed data accurately, and presented BNT to the user as intended. Tests were conducted manually, with all scenarios passing successfully. The QRS (heartbeat) detection algorithm was also rigorously evaluated against the MIT-BIH standard ECG database. It yielded a sensitivity of 99.11% and positive predictivity of 98.82%, which is comparable to most high-performing QRS detection

algorithms. The HRV analysis algorithms were tested and found to be comparable with the Kubios HRV software (University of Eastern Finland, Kuopio, Finland), a validated tool for this type of analysis.

Phase 3: Usability Study Results

A total of 6 participants completed the usability test with the *Beat* sensor system. There were 2 male and 4 female participants. The study had 1 participant in the 25-34 years age range, 2 in the 45-54 years range, 2 in the 55-64 years range, and 1 on the 65-74 years range. Participants' mobile phone use varied from no use at all (2/6) to using a mobile phone more than once a week (3/6), with the majority (4/6) finding mobile phones easy to use.

Observations and feedback were analyzed to identify issues with the sensor and the application, which were then prioritized by frequency and severity. The usability questionnaire results were compiled to get an understanding of user experience and satisfaction.

Findings

The testing identified no major issues with the *Beat* sensor, only minor issues that can easily be mitigated with simple adjustments to the design or training. Some of the participants were unsure what orientation to wear the sensor and where to place it. Participants also found it difficult to reset or power cycle the sensor. Finally, participants experienced some discomfort removing the sensor due to the adhesive electrodes pulling on hair. The issues are summarized in Table 1.

The primary issue identified with the BNT app was an inadequate level of training and education on core concepts of BNT. As a result of poor organization and presentation of information in these sections, users demonstrated a lack of understanding of those concepts. This resulted in several participants performing the exercises but being unable to fully interpret the results. Thus, they could not benefit from operant feedback and were sometimes unsure if they met their goal. Another issue was information overload on certain pages. This was a result of the user being asked to pace their breathing, view the biofeedback, and follow audio instructions, all at the same time. The issues are summarized in Table 2.

Table 1. Major issues identified with the *Beat* sensor during the usability study.

Issue #	Participants	Task	Issue
S1	P1, P5, P6	Wearing Sensor	Better guidance and training is required on how and where to wear the sensor. Wearable systems such as *Beat* should ensure that users are well trained and guided through the set up process, as they are not used to the technology being used.
S2	P1, P4	Resetting Sensor	Lack of defined controls to turn the sensor on and off caused confusion when troubleshooting issues. Simplifying a system can have consequences on intuitiveness. Therefore, designers must either make the controls salient to the users or incorporate breadcrumbs on the design, guiding the users through the process.
S3	P1, P3	Removing Sensor	Adhesive electrodes cause discomfort to users on removal. Designers of future wearable devices should keep in mind the balance between function and user perception.

Table 2. Major issues identified with the BNT app during the usability study.

Issue #	Participants	Task	Issue
A1	P1, P2, P4	Education	Poor organization and presentation of information resulted in a lack of understanding of core concepts (HRV[a], RSA) required to interpret key sections of the app (Biofeedback, BNT, performance reviews).
A2	P1, P4, P5	Biofeedback	Biofeedback mechanism (heart rate and goal) was not always clear. Users were unsure of what to expect and whether they were completing the exercise correctly. Future interventions should consider a simpler and more intuitive interface that does not require users to comprehend complex medical terminology.
A3	P1, P4, P5	Review	Interpreting the performance review was difficult. It was not immediately obvious whether user results match the goal. Similarly, users should be presented with a simple display of success, providing cues on how to improve the next time.
A4	P4	Biofeedback	Biofeedback screen with audio creates information overload. User attention is divided between paced breathing, heart rate wave, and audio instructions on stress countering steps.

[a]BNT: behavioral neurocardiac training, HRV: heart rate variability, RSA: respiratory sinus arrhythmia.

User Experience and Satisfaction

Overall, users' perceptions of the design and usability of the system were very positive. Participants found the sensor to be unobtrusive, reporting that it was compact and small and comfortable to wear and that it did not negatively affect day-to-day tasks. Participants also indicated that they would not hesitate to wear the sensor and that they did not experience any negative reactions while wearing it. However, a few participants indicated that the sensor might attract attention. Overall, the system was reported as easy to use, with high user satisfaction (4 of 6 of users were very satisfied).

In the postsession debrief interview conducted by the study coordinator, all participants stated that the system had a positive effect on their stress management, that they would use such a

system at home, and that they would use this system if it were available to them. Participants noted that the sensor was easy to use, convenient, and comfortable to wear.

Discussion

Beat Wearable Electrocardiographic Sensor

The 3 key objectives that guided the design process for the sensor were small device footprint, less weight, and a patient-friendly interface. These were identified as the most important requirements and key influencers of device acceptance on systematic literature reviews [12,13]. The results of this project indicate that the *Beat* sensor has met these objectives, which is reflected in the high user satisfaction.

All participants noted the sensor to be compact and small, and the majority of participants stated that wearing the sensor would not affect day-to-day tasks. This indicates that the sensor met its core objectives. However, it should be noted that half of the participants stated that the device attracted attention. This is possibly a result of the setup of the test and may not be representative of the design of the sensor. During the testing sessions, the sensor was kept visible to ensure it was functioning correctly. However, in the intended final use case, the participant would wear the device under their clothing and cover it up, thus making it less likely to attract attention.

The results of the study also indicated that the device was found to be well accepted with the limited sample. The majority of participants found the sensor to be comfortable and easy to use, with no negative reactions. Furthermore, the majority of participants stated that they would not hesitate to wear the device. This lack of hesitation and minimal burden on day-to-day tasks indicates that the sensor was found to be unobtrusive to users and that they would be interested in using the sensor in a home setting. This is important to gain user acceptance in use cases where long periods of monitoring are required.

These results indicate that the *Beat* sensor is a potentially viable candidate for remote patient-monitoring applications. It was comfortable and discreet, with participants having no issues wearing the sensor during the testing sessions. However, there are a few areas of improvement that should be addressed in future versions of the device.

The electrodes were found to cause discomfort when removed from skin with hair. Capacitive electrodes that collect a signal without direct skin contact or textile electrodes embedded in clothing offer some alternatives. However, these require some alternative form of adhesion to the skin to function. As this issue only affects a subset of users during sensor removal, the best possible course of action based on system characteristics that have driven the design would be to maintain the current design and focus on alternative placement options.

As currently designed, the sensor requires the application to provide guidance on how to orient the sensor on the body. Moving forward, the design of the sensor enclosure should provide users with some indication on how to place the sensor with the use of guiding labels, diagrams, and markers. This offers flexibility to users and caters to both beginner and expert users. Furthermore, it allows the sensor to be operated independently of the application, enabling other use cases.

The streaming nature of the device limited design complexity, but increased radio power consumption and limited the use of the sensor in the vicinity of a mobile phone. Future designs should incorporate on-board microcontrollers and flash memory to enable on-board processing of ECG, real-time alert notifications without a mobile phone, and storage of signals on board.

Beat Behavioral Neurocardiac Training Application

The findings of the usability study demonstrate that the BNT application design was likely patient friendly and in alignment with our initial objectives. However, during testing, areas of improvement were identified, specifically around the presentation and organization of educational information and the biofeedback interface.

BNT requires the user to understand HRV and RSA in order to complete the exercises. This is important for the user to interpret the biofeedback and get the full benefit of the program. In usability testing, it was found that several participants had trouble understanding the meaning of HRV and RSA and had difficulty interpreting the information shown on the screen. Participants expressed that the education sections were slightly overwhelming because they presented a lot of information at once, without providing sufficient opportunities for review. Some participants also indicated that audio recordings were not conducive to covering the material and inquired about a text-only option. The inadequate level of training on HRV and RSA can be traced as the root cause of the issues whereby users had trouble interpreting the biofeedback and performance review screens.

To mitigate the issues with education and provide an improved user experience, the educational components need to be restructured and simplified to be more efficient in content delivery. Currently, the application delivers educational content with audio recordings and on-screen text, with each section generally 5 minutes long and covering multiple topics. To improve content delivery, the content can be broken into small, easily digestible modules that take less than a minute or two to complete. The module should provide a more interactive and graphical experience and reduce the reliance on audio recordings. Furthermore, the content needs to be reviewed to improve organization and language and clinically screened to ensure it is consistent with guidelines for delivering BNT in the clinic setting.

The biofeedback interface displays the user's heart rate waveform to demonstrate the RSA pattern as a form of operant feedback. Users were expected to detect if their heart rate matched the provided goal heart rate waveform. Several participants faced issues interpreting the biofeedback screen and were unable to detect when they had achieved the goal. It may be useful to explore alternative display approaches such as configural displays to improve information saliency and promote the ability to see trends [22]. In configural displays, low-level data arrange in space to create higher order forms.

This can potentially be applied to biofeedback interface design by mapping the main domain constraints (RSA, changes in HRV) to geometric forms. As the user completes the breathing exercises, the system states will change over time and emergent features may appear if the user is achieving the correct breathing goal.

Limitations

The primary limitation of this study is that the user satisfaction questionnaires and interview responses could be influenced by response bias, specifically social desirability bias [23]. This is especially relevant as the interviewer was also involved in the development of the system and the effect of bias may inflate the positive responses to the system.

In addition, the evaluation was conducted in a controlled environment, which is not fully representative of the final intended user environment. Future testing should involve participants taking the system home, enabling the collection of user satisfaction data based on use in an actual home setting.

Conclusions

In this project, the *Beat* wearable sensor system was developed for the delivery of BNT in home settings for stress and blood pressure management. A mobile app guides users through BNT exercises and provides real-time HRV biofeedback using a wearable ECG sensor. The system was evaluated in a usability study, in which the overall response to the design and usability of the system was very positive, with high user satisfaction. All participants indicated that the system had a positive impact on their stress management and that they would use it at home.

The findings of the study identified areas of improvement, specifically focusing on the presentation of information during the lessons. These findings can also be fed back into the in-clinic BNT protocol to improve user experience. New features for the ECG sensor were identified that would enable future applications in remote patient monitoring. Although further iterations and refinements are possible, this system is a step forward toward providing a complementary approach to blood pressure and stress management at home.

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Conflicts of Interest

None declared.

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Abbreviations

BNT: behavioral neurocardiac training
ECG: electrocardiography
HRV: heart rate variability
ISO: International Organization for Standardization
RSA: respiratory sinus arrhythmia

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Original Paper

Behavior Change Techniques Present in Wearable Activity Trackers: A Critical Analysis

Kathryn Mercer[1], BA (Hons), MI; Melissa Li[1], PharmD; Lora Giangregorio[2], PhD; Catherine Burns[3], PhD; Kelly Grindrod[1], BSc Pharm, MSc, PharmD

[1]School of Pharmacy, University of Waterloo, Waterloo, ON, Canada

[2]Kinesiology, University of Waterloo, Waterloo, ON, Canada

[3]Faculty of Engineering, University of Waterloo, Waterloo, ON, Canada

Corresponding Author:
Kelly Grindrod, BSc Pharm, MSc, PharmD
School of Pharmacy
University of Waterloo
200 University Ave West
Waterloo, ON, N2L 3G1
Canada
Phone: 1 519 888 4567 ext 21358
Fax: 1 519 884 8009
Email: kelly.grindrod@uwaterloo.ca

Abstract

Background: Wearable activity trackers are promising as interventions that offer guidance and support for increasing physical activity and health-focused tracking. Most adults do not meet their recommended daily activity guidelines, and wearable fitness trackers are increasingly cited as having great potential to improve the physical activity levels of adults.

Objective: The objective of this study was to use the Coventry, Aberdeen, and London-Refined (CALO-RE) taxonomy to examine if the design of wearable activity trackers incorporates behavior change techniques (BCTs). A secondary objective was to critically analyze whether the BCTs present relate to known drivers of behavior change, such as self-efficacy, with the intention of extending applicability to older adults in addition to the overall population.

Methods: Wearing each device for a period of 1 week, two independent raters used CALO-RE taxonomy to code the BCTs of the seven wearable activity trackers available in Canada as of March 2014. These included Fitbit Flex, Misfit Shine, Withings Pulse, Jawbone UP24, Spark Activity Tracker by SparkPeople, Nike+ FuelBand SE, and Polar Loop. We calculated interrater reliability using Cohen's kappa.

Results: The average number of BCTs identified was 16.3/40. Withings Pulse had the highest number of BCTs and Misfit Shine had the lowest. Most techniques centered around self-monitoring and self-regulation, all of which have been associated with improved physical activity in older adults. Techniques related to planning and providing instructions were scarce.

Conclusions: Overall, wearable activity trackers contain several BCTs that have been shown to increase physical activity in older adults. Although more research and development must be done to fully understand the potential of wearables as health interventions, the current wearable trackers offer significant potential with regard to BCTs relevant to uptake by all populations, including older adults.

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KEYWORDS

older adults; physical activity; wearables; mobile health; chronic disease management

Introduction

Chronic Illness, Physical Activity, and Sedentary Behavior

Physical inactivity contributes to an estimated 3.2 million deaths each year [1]. As of 2010, almost one in four adults was receiving less than the recommended 150 minutes of moderate-intensity physical activity per week [2]. Physical inactivity is the fourth leading cause of mortality, behind only hypertension, tobacco use, and high blood glucose [3]. The prevalence of physical inactivity is increasing, and it has been identified as a major risk factor for breast and colon cancers, diabetes, and heart disease [3]. Increased exercise can reduce frailty, lower blood pressure, and lead to a longer independent life [4,5].

Sedentary behavior is an independent risk factor for chronic disease that is separate from physical inactivity. Sedentary behavior is defined as "any waking behavior characterized by an energy expenditure of < 1.5 metabolic equivalents while in a sitting or reclining posture" [6]. For example, children who watch more than 2 hours of television a day have poorer body composition, physical fitness, self-esteem, prosocial behavior, and academic achievement [7]. Sedentary behavior is also associated with metabolic syndrome and cardiovascular disease in adults independently of physical activity [8,9].

Wearable Activity Trackers

Wearable activity trackers are an emerging solution for motivating people to improve their physical activity levels and reduce sedentary behavior. Wearable trackers are activity monitors that track daily movement through sensors and companion smartphone or computer applications. As of 2015, at least half of consumers have heard of wearable activity trackers such as Fitbit or Jawbone and one in three have plans to purchase one [10]. And although the predicted buyers for most products are young people who are already living a healthy lifestyle [9], participants aged more than 60 years also appear to be receptive to using wearable activity trackers and learn to use them quite easily [10]. The newer-generation wearable activity trackers are also fairly accurate when compared with research-grade devices, [10] but only when used by people who do not have the atypical gaits often seen in those who experienced stroke or traumatic brain injury or have Parkinson's disease [11-16].

Behavior Change Techniques

One question that emerges is how well wearable activity trackers align with the evidence-based techniques that have been shown to increase physical activity levels. One approach to identifying the behavior change techniques (BCTs) present in new and emerging technologies is to use a taxonomy such as the Coventry, Aberdeen, and London-Refined (CALO-RE) taxonomy. First published in 2011, the CALO-RE taxonomy contains 40 techniques derived from behavior change theories. It was based on an earlier 26-item taxonomy developed in 2008 by Abraham and Michie [17,18] and was refined using systematic reviews of physical activity and healthy eating interventions. The CALO-RE taxonomy was designed to help developers of new interventions identify and apply evidence-based techniques [19]. In 2013, Michie et al expanded the CALO-RE taxonomy to Behavior Change Technique Taxonomy (BCTT), which contains 93 items sorted into a hierarchy and is intended for multiple behaviors and disciplines (eg, health, environment) [18,20,21]. However, unlike BCTT, CALO-RE was specifically designed for physical activity and healthy eating behaviors and continues to be widely used [19,22]. Furthermore, the CALO-RE taxonomy has been widely used to characterize physical activity interventions such as smartphone apps [21], health coaching [19], and interventions for preventing and managing obesity in children [23].

Wearable activity trackers are being targeted at users of mobile apps as a way to promote physical activity [9]. However, there are key differences between mobile apps and wearable activity trackers. Direito et al [24] found that the 40 top-rated physical activity and diet apps most commonly provided instruction, set graded tasks, and prompted self-monitoring. In a similar study of 167 physical activity apps, Conroy et al [21] also identified that it was common for apps to model or demonstrate target behaviors and provide feedback on performance. More recently, Lyons et al [25] used the BCTT to systematically analyze 13 wearable activity trackers and found that all trackers helped users to self-monitor behavior, obtain feedback on behavior, and add objects to the environment while also generally supporting users in goal setting and comparing their behavior with their goal. Lyons et al [25] also found that wearable activity monitors contain a wide range of techniques that are typically used in clinical behavioral interventions and that the trackers are a medium by which these interventions may be translated into widespread use. However, one aspect not addressed by the above studies is self-efficacy. In recent years, self-efficacy has emerged as a priority for improving physical activity in older adults. Self-efficacy is "the belief in one's capabilities to organize and execute the courses of action required to produce given attainments" [26]. Theoretically, people who have a high self-efficacy for physical activity should be more likely to initiate, increase, and maintain physical activity, even in the face of obstacles and setbacks [26]. A 2011 systematic review identified self-efficacy as one of the most consistent predictors of physical activity in adults of all ages [27]. A 2009 literature review of interventions for older adults also found that self-efficacy was one of the most intensely studied and constant predictors of physical activity maintenance [28]. Furthermore, a 2014 systematic review by French et al [20] concluded that self-regulation techniques such as goal setting, feedback, and social support are effective for younger adults, whereas older adults may benefit more from problem-solving, rewards for successful behavior, and modeling or demonstrating behavior. Therefore, the objective of this study was to use the CALO-RE taxonomy to examine whether the design of wearable activity trackers incorporates BCTs. A secondary objective was to critically analyze if the BCTs present relate to known drivers of behavior change in older adults, such as self-efficacy.

Methods

We ran this study concurrently with another study examining the real and perceived acceptance of wearable activity trackers

by older adults (aged more than 50 years) living with chronic illness [29]. We wanted to analyze BCTs as they relate to the overall population, an added nod to the applicability to the older adult population. The team of researchers included a pharmacist (KG), a pharmacy student (ML), two systems design engineers (CB and LR), a kinesiologist (LG), and an information specialist (KM). We used the same trackers for both studies, as they reflected the available wearable fitness trackers in Canada. Our inclusion criteria for the wearable activity trackers included (1) continuous monitoring of some kind of physical activity outcome (steps, minutes of activity, points) and (2) provision of feedback via a separate mobile device or personal computer. We considered a device to be a wearable activity tracker if it contained an accelerometer and connected with a mobile platform. The device also had to be able to be wirelessly paired with handheld or desktop computers with at least Bluetooth 2.0 and be compatible with either Android 1.6+ or Apple's operating system iOS 6.0+. The following wearable activity trackers were evaluated for BCT content: Misfit Shine, Fitbit Flex, Jawbone UP24, Withings Pulse, Nike+ FuelBand SE, Polar Loop, and SparkPeople (Figure 1).

Figure 1. Wearable fitness trackers. Top L-R: Jawbone UP24, Nike Fuelband, Polar Loop, Misfit Shine with sport band . Centre: Misfit Shine with action Clip. Bottom L - R: Withings Pulse, Fitbit Zip, Spark Activity Tracker.

Rating

We coded the wearable activity trackers using the CALO-RE taxonomy, which is a standardized tool for describing and comparing the BCTs used in lifestyle interventions [17]. As a test for calibration, the mobile apps Runkeeper and MyFitnessPal were coded using the CALO-RE taxonomy. To resolve differences in interpretation between raters, we discussed any ambiguous descriptors or definitions from the CALO-RE taxonomy until we reached agreement during the calibration process. This is correct For each wearable activity tracker, we downloaded the associated mobile app onto an Apple device (iPad mini, iPhone 5) and/or an Android device (Samsung Galaxy S4 smartphone or Google Nexus tablet). Two independent raters (ML and KG) wore each activity tracker for 1 week between May and August 2014 and rated the seven activity trackers and their associated mobile/Web-based platforms using the CALO-RE taxonomy. Images and website links that indicated the presence of a BCT were compiled during ratings and used later in discussion to resolve any conflicts between raters. If consensus was not reached after consulting the referenced item, a third user, who had used the activity tracker for at least 1 month, was brought in to resolve the disagreements. With 1 month of use, the third user was more likely to have been exposed to all possible taxonomy elements, if present, in the device.

We coded each technique using a dichotomous score of either 0 (not present) or 1 (present). For mobile apps and websites that had archives of information articles, we only coded a technique if the user was prompted to read a specific article or community post through an email alert or daily message. Upon installation of certain mobile apps, animations would prompt users to look at specific tabs and features or everything listed in the main menu. If any of these elements fit in with a BCT, it was also coded. We did not consider any information that was not

immediately accessible or that was not presented through prompting.

Statistical Analysis

We used descriptive statistics to summarize the CALO-RE ratings. We calculated interrater reliability using Cohen's kappa on SPSS Statistics (version 22, IBM). Cohen's kappa is used to describe the degree of interrater reliability between two raters and can be applied to dichotomous data [30]. We also calculated the total number of techniques present in each activity tracker and the frequency of each technique.

Results

Rating

Seven wearable activity trackers were rated by two independent raters using the 40-item CALO-RE taxonomy [18]. The number of BCTs ranged from 10 to 23, the most common shown in Figure 2. The 40 BCTs rated in each tracker were based on the CALO-RE taxonomy and included consequences of behavior, goal setting, problem-solving, outcome review, prompting, practicing, teaching, and social encouragement. As shown in Figure 2, a total of 9 techniques were present in every tracker. All trackers prompt users to self-monitor their activity levels, review goals, and review past successes while also providing feedback on performance, either by comparing step counts with user goals or by sending summary emails on activity levels over a certain period of time (daily, weekly, monthly). All trackers also included an optional social component to help users see others' approval or to plan for social support and change. Six trackers encouraged users to set a physical activity goal. Seven BCTs that were used less commonly included focusing on past and future performances, teaching prompts and cues, and instructing on how to perform a behavior.

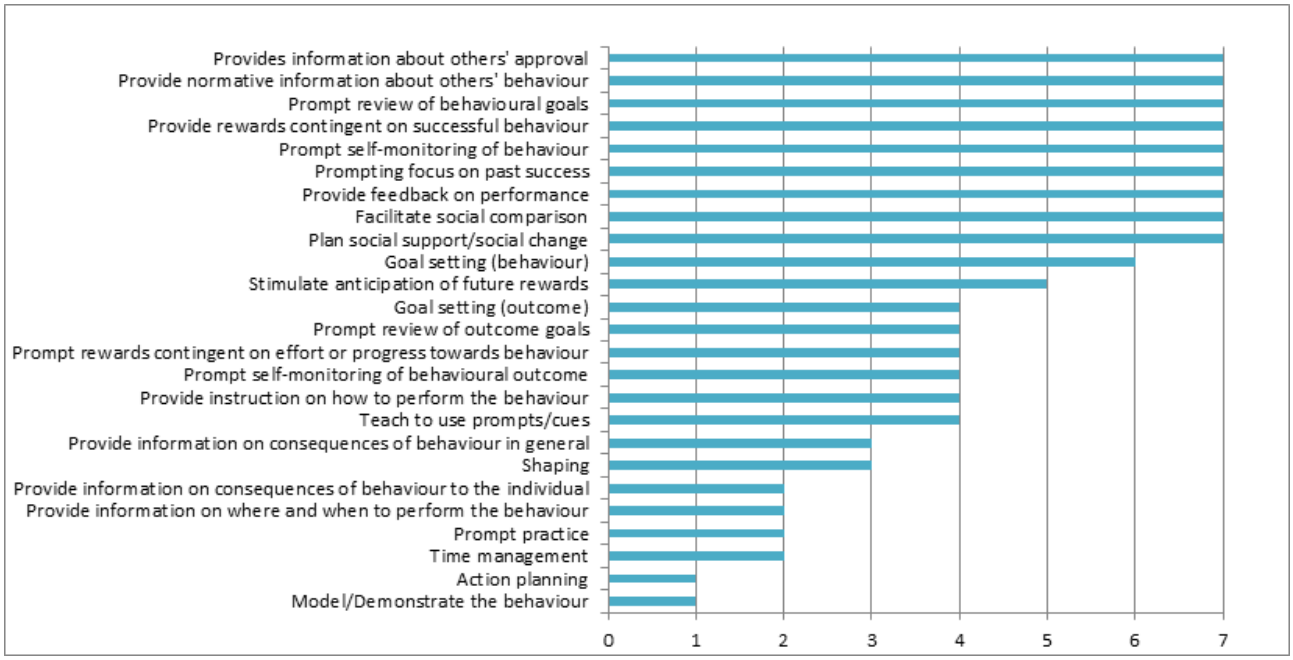
There were 15 techniques absent in all wearable activity trackers, as listed in Textbox 1. The missing techniques were related to self-efficacy, planning, negative feelings (eg, fear), consequences, and comfort zones.

Textbox 1. Behavior change techniques absent in wearable activity trackers.

Behavior change techniques absent

- Barrier identification or problem-solving
- Set graded tasks
- Prompting generalization of a target behavior
- Environmental restructuring
- Agree behavioral contract
- Use of follow-up prompts
- Prompt identification as role model or position advocate
- Prompt anticipated regret
- Fear arousal
- Prompt self-talk
- Prompt use of imagery
- Relapse prevention or coping planning
- Stress management or emotional control training
- Motivational interviewing
- General communication skills training

Figure 2. Most common behavior change techniques; with total number of devices found in.



Statistical Analysis

The kappa scores for interrater reliability of the taxonomy for the seven wearable activity trackers ranged from .746 to 1 (Table 1) [31]. According to the benchmarks assigned by Landis and Koch [30], the strength of agreement is "substantial" to "almost perfect."

Table 1. Interrater reliability of taxonomy per wearable activity tracker

Wearable activity tracker	Cohen's kappa (95% CI)
Fitbit Flex	1 (0.00)
Jawbone UP24	.899 (0.764-1.034)
Misfit Shine	1 (0.00)
Nike+ FuelBand SE	.944 (0.836-1.052)
Polar Loop	.881 (0.722-1.040)
SparkPeopl Spark Activity Tracker	.746 (0.544-0.948)
Withings Pulse	.899 (0.764-1.034)

The mean number of BCTs incorporated in wearable activity trackers was 16.3/40 (SD 4.6), with Withings Pulse having the highest number at 23/40 and Misfit Shine having the lowest at 10/40 (Table 2). In case of Withings Pulse, most of the techniques, particularly those that focused on the provision of information, were addressed in a comprehensive "Frequently Asked Questions" section of the mobile app. All of the BCTs coded this way were related to the provision of information, such as "provide instruction on how to perform the behavior." In comparison, for the SparkPeople device, which had 21/40 BCTs, most techniques were found in articles and videos available on the Web-based platform, which were brought to the attention of the user via email notifications. Misfit Shine and Polar Loop bands incorporated the lowest number of techniques, with only 10/40 and 13/40 techniques, respectively. This in part can be explained by the absence of outcome goals (eg, weight), minimal information in the accompanying mobile apps and websites, and a lack of a virtual reward system.

Table 2. Behavior change technique content of wearable activity trackers, mean 16.3 (SD 4.6).

Wearable activity tracker	Number of behavior change techniques (N=40)	Possible behavior change techniques present (%)
Withings Pulse	23	57.5
SparkPeople Spark Activity Tracker	21	52.5
Jawbone UP24	18	45.0
Fitbit Flex	15	37.5
Nike+ FuelBand SE	14	35.0
Polar Loop	13	32.5
Misfit Shine	10	25.0

Discussion

Many of the newest generation wearable activity trackers include BCTs in the user interface. Results from the CALO-RE taxonomy ratings demonstrated that the devices tend to focus on techniques for goal setting, self-regulation, and social support. Techniques related to self-efficacy (such as planning, consequences, and knowledge) were present in less than half of the trackers or absent in all seven devices.

Our findings were similar to the ratings of activity trackers by Lyons et al [25]. However, there are some notable differences. For example, in our study, none of the reviewers identified problem-solving as a feature in the Jawbone tracker, whereas the coders in the study by Lyons et al did. Although Lyons et al [25] used the 93-item taxonomy, they recalculated their results with the CALO-RE taxonomy and found an average of 9 techniques across 13 activity trackers. In comparison, we found an average of 16 techniques, which suggests that identification of BCTs depends on how users experience the devices. While rating these devices, we were also actively testing the devices with individuals aged more than 50 years who were living with chronic illness. By concurrently using the devices alongside active users, we may have had the opportunity to identify more features than if we had limited our use of the trackers to the research team.

In previous evaluations of physical activity interventions among adults aged 50 years and older, social support from peer mentors, families, and friends significantly increased initiation and maintenance of physical activity [32]. Online communities have also been associated with increasing step counts in walking programs in study participants with an average age of 50 years and greater [33]. Behavior change techniques relating to social support were present in every wearable activity tracker and associated platforms through online communities and connectivity to popular social media networks.

A 2014 systematic review by French et al [20] identified that the three BCTs with the greatest effect on physical activity in older adults are problem-solving, rewards for successful behavior, and modeling or demonstrating the behavior. We found that rewards were present in all seven trackers, while behavior modeling was only present in one tracker, and problem-solving was not present in any of the trackers. French et al [20] also identified that interventions had the greatest effect on older adults when they provided a combination of normative information about others' behavior and information on where and when to perform behavior and helped participants plan social support or social change. We also found that two techniques (information about others' behavior and planning) were present in all seven trackers but that only two trackers helped users identify where and when to perform the behavior.

Self-efficacy is an important predictor for starting and maintaining physical activity in adults aged more than 50 years [28]. However, the effect of wearable activity trackers on self-efficacy is not clear, as O'Brien et al found no increase in physical activity self-efficacy in a 12-week study of older adults using Nike FuelBand [10]. The systematic review by French et al [20] found that the techniques associated with greater self-efficacy include prompt use of imagery, motivational interviewing, and prompt generalization of target behaviors, none of which were identified in the trackers in our study. This suggests that there is potential if self-efficacy techniques are increased in wearable activity trackers for increase in physical activity.

The focus of wearable activity trackers on self-monitoring and self-regulation is to be expected. The main design and purpose of these devices is to monitor past, present, and future activity. A qualitative analysis of an 18-month physical activity intervention in older adults found that targeting self-regulation behaviors may support long-term increases in physical activity [32]. All but one tracker required users to set an activity goal, often in the form of steps per day. Goal setting may also significantly increase physical activity among older adults, particularly if goals are specific and related to the desired behavior [20].

Limitations

Although we had a high interrater reliability, the ratings may not represent the most current version of the wearable activity tracker and associated platforms because of frequent updates. We minimized these elements by ensuring that all notifications were enabled, saving screenshots and website links representing each technique, consulting an experienced tracker user when necessary, and downloading all updates as of August 8, 2014. This method of evaluating the physical tracker and downloaded platforms allowed us to identify more BCTs than if Web-based descriptions alone were used, which was the approach used by

Conroy et al [21] to rate mobile apps for physical activity using the CALO-RE taxonomy.

One challenge for studies of this nature is that there is no guarantee that the user will encounter a technique even if it is present. For example, if a user does not wish to use or does not have access to social media, then the user will not encounter any of the tracker's social support techniques. A further challenge for rating trackers is that they are complex tools with multiple features and different users are likely to have different experiences. For example, a user who wants to perform more physical activity may not use the device in the same way as a user who wants to be less sedentary. Similarly, a user who has a lower health or technology literacy may not explore the features as deeply as a health professional or expert technology user, regardless of age. As a result, this study should be considered a snapshot of the BCTs of wearable activity trackers and of the potential of how these trackers can relate to self-efficacy in the older user. By determining the similarities and differences between the overall population and the older adult population, there is great potential to develop wearable activity trackers and their affiliated apps to be the most broadly reaching.

Conclusions

Wearable activity trackers are a promising innovation for promoting physical activity behaviors in a wide age range of users, including the older adult population. They can easily be distributed across a wide population and integrated as a part of physical activity interventions through pharmacies and prescribers. Behavior change techniques most commonly found in the evaluated wearable activity trackers, such as self-monitoring and self-regulation techniques, are likely to appeal more to younger and middle-aged adults. To make wearable activity trackers more appealing to older adults, additional BCTs that are specific to older adult needs may be necessary, such as helping users find ways to overcome barriers to physical activity by problem-solving and modeling or demonstrating ways to increase physical activity. Future collaborations between tracker developers and health behavior change experts may enhance the potential to elicit behavior change.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CALO-RE Taxonomy Rating Data.

[PDF File (Adobe PDF File), 30KB - mhealth_v4i2e40_app1.pdf]

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Abbreviations

BCT: behavior change technique
BCTT: Behavior Change Technique Taxonomy
CALO-RE: Coventry, Aberdeen, and London-Refined

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Toronto, ON, M5A 3Y5
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